

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

MDL. NO. 1456

THIS DOCUMENT RELATES TO:

Civil Action No. 01-CV-12257- PBS

COUNTY OF WESTCHESTER v. ABBOTT LABORATORIES, INC., et al.

Judge Patti B. Saris

S.D.N.Y. Case No. 03-cv-6178

AMENDED COMPLAINT

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The County of Westchester (“Westchester”), by its attorneys, KIRBY, McINERNEY & SQUIRE, LLP, for its complaint against the above-named defendants, alleges, on information and belief, as follows:

I. INTRODUCTION

1. Westchester brings this action against the defendant manufacturers of prescription drugs to recover monetary damages, and for civil penalties, declaratory and injunctive relief, restitution, disgorgement of profits, and treble and punitive damages suffered by it and by the State and federal governments from 1992 to the present as a result of defendants’ fraudulent and misleading schemes that overcharge the New York State Medicaid program (“Medicaid program”) for prescription drugs bought on behalf of Westchester residents who receive Medicaid benefits.¹

2. Westchester, in its role as a Local Social Services District, plays an integral part in the administration of the Medicaid program for Westchester residents, and pays approximately 25 percent of the Medicaid costs of those residents. N.Y. Soc. Serv. L. §§ 367-a and 368-a; 42 U.S.C. §1396d(b). The State pays another 25 percent, and the federal government pays 50 percent. The Westchester Medicaid program paid over \$103.7 million for prescription drugs for Westchester residents in 2003.

3. There are two components of the price Medicaid pays for prescription drugs. The first is the price initially paid by Medicaid to the provider – generally a dispensing pharmacy – of the drug. This price is determined by a formula contained in New York State law, and is based on price information provided by the manufacturers. N.Y. Soc. Serv. L. §367-a(9). The second component is a rebate that drug manufacturers pay to the states

¹ The New York State Medicaid program for Westchester residents is sometimes referred to hereinafter as the “Westchester Medicaid program.”

pursuant to a federal statutory formula, 42 U.S.C. § 1396r-8 (the “Medicaid rebate provision”), and pursuant to statutorily mandated Medicaid rebate contracts that each manufacturer executes with the Secretary of Health and Human Services “on behalf of the States.” Model Rebate Agreement at 1.² The amount of the rebate is calculated by the various manufacturers based on price information provided by the manufacturers and utilization data provided by the State Medicaid Plans.

4. Defendants’ fraudulent schemes involve both components. Their manipulation of the Medicaid program through fraudulent inflation of the various pricing information that forms the bases for each of these two components has resulted in overcharges of many millions of dollars to the Westchester’s Medicaid program.

A. FRAUDULENT INFLATION OF THE PRICE INITIALLY PAID BY MEDICAID

5. Under New York State law, the initial price paid by Medicaid to the dispensing pharmacy is determined by the Average Wholesale Price (“AWP”), a price that is published by several industry publishing services based wholly on information supplied by the drugs’ manufacturers. N.Y. Soc. Serv. L. §367-a(9). AWP is defined in industry publications as an average cost paid by pharmacies to pharmaceutical wholesale suppliers. The publishing services publish AWP’s for each specific dosage and packaging of each drug.

6. AWP is not only used by Medicaid. It is also the basis for reimbursement by private insurers, self-insured employers (both also known as “third-party payors”), pharmacy benefits managers (“PBMs”) and other drug payors. Reliance on AWP is fostered

² See 56 FR 7049 (Feb. 21, 1991) (reprinting text of the Model Rebate Agreement); 60 FR 48442 (Sept. 19, 1995) (discussing Model Rebate Agreement). A copy of the current standard Model Rebate Agreement, available at <http://www.cms.hhs.gov/medicaid/drugs/drebate.asp>, and substantially similar to that executed by each defendant named herein, is annexed hereto as Exhibit E.

by the fact that defendants keep more accurate pricing information from the states and other payors.

7. Both pharmacists and PBMs frequently play roles in deciding which drug a patient ultimately receives. The PBM does this by including or not including a brand name drug on a formulary of drugs that its health plan clients pay for. The PBM selects the brand name drug for its formulary based on spread and rebate. The pharmacist does this by selecting among competing generic drugs in cases where such competition exists or selecting and/or promoting particular prescription drugs. The pharmacist stocks the generic option with the largest spread. Often, the PBM will also act as a mail order pharmacy, and can then collect both the PBM's profit and the pharmacist's. Wholesalers likewise establish formularies and auto-substitution programs and otherwise make efforts to promote particular drugs so as to maximize their profits.

8. Defendants provide grossly inflated pricing information to the publishing services, causing them in turn to publish similarly inflated AWP's. Their purpose in doing so is to create a large spread between the actual price that providers such as pharmacists pay to acquire drugs and the reimbursement that those same entities receive from Medicaid, Medicare and private third party payors. Defendants advertise this spread as a reason why those in the distribution chain should sell their drugs, a practice is known as "marketing the spread." The spread is an incentive, in effect a bribe, to any in the distribution chain – pharmacy chains, PBMs, insurers – who are able to increase demand for a defendant's drugs and to select that defendant's drugs over competing drugs. Through defendants' manipulation of AWP, they induce the Medicaid program, as well as Medicare and private payors, to pay this unlawful incentive for the purchase of defendants' products.

9. Defendants inflate and manipulate the spread for both brand name and generic drugs. With generic drugs, competition provides an obvious motive to increase the spread. There is on average more divergence between the actual price and the AWP for generic drugs than there is for brand name drugs. A 2002 government report analyzing 1999 data found that pharmacists paid on average only 34.1% of AWP for generic drugs. For brand name drugs pharmacists paid on average only 78.2% of AWP. Department of Health and Human Services, Office of Inspector General of the (“HHS OIG”), Medicaid Pharmacy-Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products (Sept. 16, 2002) (A-06-02-00041).

10. However, the incentive to maintain and increase spread is not limited to generic drugs for which there is direct competition in the form of bioequivalent drugs. Brand name drugs protected by patent frequently face competition from other brand name or generic drugs aimed at similar illnesses. Moreover, even absent competition, all manufacturers seek to increase demand for their products. Like direct to consumer advertising and other marketing efforts, manipulating the spread is a way to accomplish this.

11. These practices have been uncovered by recent government investigations, by litigation, and by the press. On December 7, 2004, the House Subcommittee of Oversight and Investigation of the Commerce and Energy Committee conducted a hearing on “Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much.” In his opening remarks, Chairman Joe Barton (R-TX) stated:

During the course of this investigation, the committee has uncovered evidence that several manufacturers either inflate their AWP's or actively market their products, not based on the lowest price, but on the difference between price and the reimbursement amount, better known in the industry as the spread. . . . Data obtained by the committee from five of the largest retail pharmacy

chains reveals that during the period of July 1, 2002 to June 20, 2003, the average acquisition costs for seven widely prescribed generic drugs was 22 cents, while the average Medicaid reimbursement just for those drugs alone was 56 cents, more than double the cost

Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much: Hearing Before the House Subcomm. on Oversight and Investigations, 108th Cong. Transcript. (“Tr.”) 3-4, 5 (2004) (statement of Joe Barton, Chairman, House Subcomm. on Oversight and Investigations).

12. The Wall Street Journal described one set of contracts involved in the sale of the antidepressant and antiobsessional generic drug fluoxetine, one of the drugs at issue here, manufactured by Defendants Barr, Novartis, Par and Teva. *See Rx for Margins: Hired to Cut Costs, Firms Find Profits In Generic Drugs, Pharmacy-Benefit Managers Can Take Huge Markups And Still Offer ‘Discounts,’ Making \$170 On Just 90 Pills*, WSJ., March 31, 2003, at A1. The AWP for fluoxetine was \$2.66 per pill. The pharmacist could purchase fluoxetine for approximately 5 cents per pill. According to the Wall Street Journal, the health plan paid AWP minus 73%, or 60 cents per pill, to a PBM, ExpressScripts, which in turn contracted with dispensing pharmacists approved by it to pay them 25 cents per pill, or AWP minus 94%. The PBM’s profit was 35 cents per pill, and the pharmacist’s profit was 20 cents per pill.

13. In 2002 alone, Westchester spent over \$652,000 on fluoxetine. *See* Exhibit A to this Complaint (showing the Westchester’s expenditures during the calendar year 2002 for each of the drugs at issue herein). Westchester was overcharged between 56% and 95% on each pill as a result of the false fluoxetine AWP. *See* Exhibit B to this Complaint (estimating AWP spread for certain major drugs).

B. FRAUDULENT UNDERPAYMENT OF REBATES

14. The second component of Medicaid prescription drug costs concerns the federally mandated rebate that drug manufacturers are required to pay to the states based on price information provided quarterly by the manufacturers. 42 U.S.C. § 1396r-8. The rebate for brand name drugs (defined as “single source drugs” or “innovator multiple source drugs”) is statutorily defined as the difference between two prices: the Best Price and the Average Manufacturer’s Price (“AMP”).³ Best Price is the lowest price paid by any purchaser. AMP is the average price paid to the manufacturer by wholesalers. See 42 U.S.C. § 1396r-8(c)(1)(C) (defining Best Price); 42 U.S.C. § 1396r-8(k)(1) (defining AMP). The lower the Best Price for a particular drug, the greater the rebate will be.

15. Defendants unlawfully reduce the amounts of rebates that they pay to the states for brand name drugs by omitting from their computations of Best Price statutorily and contractually required information. For example, defendants omit from their rebate calculations routine discounts, such as volume discounts, the customary two-percent prompt pay discount, chargebacks, rebates, free samples and other off-invoice transactions and inducements offered to create market share and demand for their products. The U.S. Senate is currently investigating defendants’ omissions of certain discounted commercial sales, which defendants unlawfully seek to shoehorn within the “nominal price” exception to Best Price calculations.⁴ Defendants also fail properly to allocate discounts in bundled sales (*i.e.*, sales where a variety of defendants’ drugs are sold for a single bundled price).

³ The rebate for other drugs is 11.1% of AMP. 42 U.S.C. § 1396r-8(c)(3); N.Y. Soc. Serv. L. § 367 (a)(7)(d).

⁴ The Medicaid statute permits pharmaceutical manufacturers to exclude from their Best Price calculations drugs with prices less than 10% of AMP. 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(III). This exception permits drug manufacturers to continue to sell drugs at nominal prices to entities serving the public good without including those sales in their Best Price calculations (and therefore without causing defendants to pay higher rebates). However, certain manufacturers have abused the exception to hide commercial discounts.

16. A 2001 report issued by the Department of Health and Human Services (“HHS”) found that many manufacturers had excluded from their Best Price calculations the discounted prices paid by HMOs, which were as much as 75 percent below the reported Best Price. See Medicaid Drug Rebates – Sales to Repackagers Excluded From Best Price Determinations, HHS Office of the Inspector General (Mar. 27, 2001).

17. In 2003, two defendants herein, Bayer and GlaxoSmithKline, agreed to pay \$346 million to resolve allegations that they defrauded Medicaid and Medicare by engaging in a scheme known as “lick and stick,” wherein they relabeled their products before selling them to Kaiser Permanente Medical Care Program (the nation’s largest HMO) at deep discounts, in order to exclude these discount-priced sales in computing and reporting their Best Prices.

18. Numerous federal criminal and civil prosecutions illustrate that fraud with respect to both components of Medicaid pricing is pervasive among defendants. Defendant Abbott is paying \$621 million in criminal and civil penalties for defrauding Medicare and Medicaid and has affirmatively acknowledged its involvement in the fraud. Defendant Bristol Myers is under investigation in connection with its pricing practices for drugs covered by Medicare and Medicaid. Defendant AstraZeneca paid \$355 million to settle federal fraud charges that it induced doctors to falsely bill Medicare and Medicaid. Defendant Schering-Plough has agreed to pay nearly \$350 million in fines and damages, and to plead guilty to criminal charges that it defrauded Medicaid. Defendant TAP Pharmaceuticals paid \$875 million in connection with its fraudulent pricing practices respecting Lupron. Defendant Warrick paid \$27 million to the state of Texas to resolve allegations that it reported fraudulent price information to Medicaid. Defendant Dey paid \$18 million to settle similar claims of

defrauding Medicaid in Texas. *See* Exhibit B and Exhibit D (detailing investigations and lawsuits against defendants named herein for unlawfully inflating Medicaid prices based on AWP and understating the true amounts of rebates owed to the states).

19. As a result of defendants' fraudulent and illegal manipulation of Medicaid drug prices, defendants have reaped billions of dollars in illegal profits. By this action, Westchester seeks (1) recovery of the excessive Medicaid pharmacy costs paid on behalf of Westchester residents by Westchester, the State of New York, and the United States as a result of defendants' intentional misconduct; (2) payment of the full amount of rebates owed; (3) disgorgement of defendants' unlawful profits; (4) punitive damages; and (5) entry of an order directing defendants henceforth to report accurate wholesale price information and Best Prices and pay correct rebates in compliance with federal and state statutes.

II. JURISDICTION AND VENUE

20. Plaintiff claims violations of, *inter alia*, the Social Security Act, 42 U.S.C. § 1396 *et seq.*, N.Y. Social Services Law §§ 145-b and 367a, and N.Y. General Business Law § 349, and breach of contract, unjust enrichment, and common law fraud.

21. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because the action alleges violations the Social Security Act, 42 U.S.C. § 1396 *et seq.* This Court has supplemental jurisdiction over Westchester's state law claims pursuant to 28 U.S.C. § 1367.

22. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) because defendants do business and are qualified to do business in this district; certain acts giving rise to the claims asserted in this complaint occurred within this district; and the illegal actions of defendants, as alleged in this complaint, caused damage to plaintiff within this district.

III. PARTIES

23. Plaintiff, the County of Westchester, is a municipal corporation organized pursuant to the laws of the State of New York. By statute, Westchester pays 25% of Medicaid prescription drug costs. N.Y. Soc. Serv. L. §§ 367-a and 368-a.

24. Defendants are manufacturers and sellers of prescription drugs. Each defendant conducts extensive business in the State of New York, including in Westchester. Each defendant manufactures, markets and sells prescription drugs with false and inflated wholesale prices that are paid for by Medicaid in Westchester.

25. Defendant Abbott Laboratories, Inc. (“Abbott”) is an Illinois corporation engaged in the business of manufacturing and selling pharmaceuticals. Abbott’s principal place of business is located at 100 Abbott Park Road, Abbott Park, IL. Abbott Pharmaceuticals (“Abbott Pharm”) is the pharmaceutical division of Abbott.

26. Defendant Alcon Laboratories, Inc. (“Alcon”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Alcon’s principal place of business is located at 6201 S. Freeway (T1-3), Fort Worth, TX, 76115.

27. Defendant Allergan, Inc. (“Allergan”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Allergan’s principal place of business is located at 2525 Dupont Drive, Irvine, CA 92612.

28. The following two defendants are hereinafter referred to as the Alpharma Group:

(a) Defendant Alpharma, Inc. (“Alpharma”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Alpharma’s principal place of business is located at One Executive Drive, Fort Lee, NJ 07024.

(b) Defendant Purepac Pharmaceutical Co. (“Purepac”), a wholly owned subsidiary of Alparma, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Purepac was acquired by Alparma in December 2001. According to the SEC, Purepac’s principal place of business is located at One Executive Drive, Fort Lee, NJ 07024.

29. The following two defendants are hereinafter referred to as the Amgen Group:

(a) Defendant Amgen, Inc. (“Amgen”) is a Delaware corporation in the business of manufacturing and selling pharmaceuticals. Amgen’s principal place of business is located at One Amgen Drive, Thousand Oaks, CA 91320-1799.

(b) Defendant Immunex Corporation (“Immunex”), a wholly owned subsidiary of Amgen since July 2002, is a Washington State corporation engaged in the business of manufacturing and selling pharmaceuticals. Immunex’s principal place of business is located at 51 University Street, Seattle, WA 98101.

30. Defendant Andrx Corporation (“Andrx”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Andrx’s principal place of business is located at 4955 Orange Drive, Davie, FL 33314.

31. Defendant AstraZeneca Pharmaceuticals L.P. (“Astrazeneca”) is a Delaware limited partnership engaged in the business of manufacturing and selling pharmaceuticals. AstraZeneca’s principal place of business is located at 1800 Concord Pike, Wilmington, DE 19850-5437.

32. The following two defendants are hereinafter referred to as the Aventis Group:

(a) Defendant Aventis Pharmaceuticals Inc. (“Aventis Pharm”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Aventis Pharm’s principal place of business is located at 300-400 Somerset Corporate Boulevard, Bridgewater, NJ 08807-2854.

(b) Defendant Dermik Laboratories, Inc. (“Dermik”), a wholly owned subsidiary of Aventis Pharm, is a Pennsylvania corporation engaged in the business of manufacturing and selling pharmaceuticals. Dermik’s principal place of business is located at 1050 Westlakes Drive, Berwyn, PA 19312.

33. Defendant Barr Laboratories, Inc. (“Barr”) is a New York corporation engaged in the business of manufacturing and selling pharmaceuticals. Barr’s principal place of business is located at 2 Quaker Road, P.O. Box 2900 Pomona, NY 10970-0519.

34. Defendant Baxter International, Inc. (“Baxter Int’l”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Baxter’s principal place of business is located at One Baxter Parkway, Deerfield, Illinois. Defendant Baxter Healthcare Corporation (“Baxter Healthcare”) is the principal domestic operating subsidiary of Baxter Int’l and located at the same address. Baxter Int’l and Baxter Healthcare are collectively referred to herein as “Baxter.”

35. Defendant Bayer Corporation (“Bayer”) is an Indiana corporation engaged in the business of manufacturing and selling pharmaceuticals. Bayer itself is a wholly owned United States subsidiary of a German corporation, Bayer AG. Bayer’s principal place of business is located at 100 Bayer Road, Crafton, PA 15205-9741. Bayer’s Pharmaceutical subsidiary (“Bayer Pharm”) is located at 400 Morgan Lane, West Haven, Connecticut.

36. Defendant Berlex Laboratories, Inc. (“Berlex”) is a Delaware corporation engaged in the business of developing, manufacturing and selling pharmaceuticals. Berlex’s principal place of business is 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

37. Defendant Biogen Idec, Inc. (“Biogen Idec”) is a Delaware Corporation engaged in the business of developing, manufacturing and selling pharmaceuticals. Biogen Idec’s principal place of business is 14 Cambridge Center, Cambridge, Massachusetts 02142. Biogen Idec was formed through the November 2003 merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation.

38. Defendant Biovail Pharmaceuticals, Inc. (“Biovail”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Biovail is a wholly owned subsidiary of Biovail Corporation, a Canadian corporation whose principal offices are located at 7150 Mississauga Road, Mississauga, Ontario, Canada, L5N 8M5. Biovail’s principal place of business is located at 700 Route 202/206 North Bridgewater, NJ 08807.

39. The following four defendants are hereinafter referred to as the Boehringer Group:

(a) Defendant Boehringer Ingelheim Corporation (“Boehringer”) is a Nevada corporation engaged in the business of manufacturing and selling pharmaceuticals. Boehringer’s principal place of business is located at 900 Ridgebury Rd., Ridgefield, CT 06877.

(b) Defendant Boehringer Ingelheim Pharmaceuticals, Inc. (“Boehringer Pharm”), a wholly owned subsidiary of Boehringer, is a Connecticut corporation engaged in the

business of manufacturing and selling pharmaceuticals. Boehringer Pharm's principal place of business is located at 900 Ridgebury Rd., Ridgefield, CT 06877.

(c) Defendant Roxane Laboratories, Inc. ("Roxane"), a wholly owned subsidiary of Boehringer, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Roxane's principal place of business is located at 1809 Wilson Rd., Columbus, OH 43216-6532.

(d) Defendant Ben Venue Laboratories, Inc. ("Ben Venue"), a wholly owned subsidiary of Boehringer, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Ben Venue's principal place of business is located at 300 Northfield Road, Bedford, OH 44146.

40. The following two defendants are hereinafter referred to as the BMS Group:

(a) Defendant Bristol-Myers Squibb Company ("Bristol-Myers") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Bristol-Myers' principal place of business is located at 345 Park Avenue, New York, NY 10154-0037. Westwood-Squibb ("Westwood") is a division of BMS.

(b) Defendant Oncology Therapeutics Network Corp. ("OTN"), a wholly owned subsidiary of Bristol-Myers, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. OTN's principal place of business is located at 395 Oyster Point Boulevard, Suite 405, South San Francisco, CA 94080.

41. Defendant Dey Inc. ("Dey"), formerly Dey Laboratories, a/k/a Dey, L.P., is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Dey is an indirect subsidiary of Merck KGaA, a German pharmaceutical

conglomerate. Dey's principal place of business is located at 2751 Napa Valley Corporate Drive, Napa, CA 94558.

42. Defendant Eisai Inc. ("Eisai") is a Delaware corporation. It is a U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd. Eisai's principal place of business is located at 500 Frank W. Burr Boulevard, Teaneck, NJ 07666.

43. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation engaged in the business of manufacturing and selling pharmaceuticals. Eli Lilly's principal place of business is located at Lilly Corporate Center, Indianapolis, IN 46285. Eli Lilly conducts extensive business in the State of New York, including in Westchester. Eli Lilly manufactures and sells prescription drugs with false and inflated wholesale prices that are paid for by Medicaid in Westchester. Dista is a division of Eli Lilly.

44. Defendant Endo Pharmaceuticals Inc. ("Endo"), a subsidiary of Endo Pharmaceuticals Holdings Inc., is a Delaware corporation. Endo's principal place of business is located at 100 Painters Drive, Chadds Ford, PA 19317.

45. Ethex Corporation ("Ethex"), a wholly owned subsidiary of KV Pharmaceutical Company ("KV"), is a Delaware corporation with its principal place of business at 10888 Metro Court, St. Louis, MO. KV is also a Delaware corporation with its principal place of business at 2503 South Hanley Road, St. Louis, MO. Ethex is in the business of manufacturing, marketing and selling prescription pharmaceuticals.

46. The following two defendants are hereinafter referred to as the Forest Group:

(a) Defendant Forest Laboratories, Inc. (“Forest”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Forest’s principal place of business is located at 909 Third Ave, New York, NY 10022.

(b) Defendant Forest Pharmaceuticals, Inc. (“Forest Pharm”) is a corporation engaged in the business of manufacturing and selling pharmaceuticals. Forest Pharm is headquartered in St. Louis, Missouri and is a wholly owned subsidiary of Forest Laboratories, Inc. Forest Pharm’s principal place of business is located at 13600 Shoreline Drive, St. Louis, MO 63045.

47. The following two defendants are hereinafter referred to as the Fujisawa Group:

(a) Defendant Fujisawa Healthcare, Inc. (“Fujisawa”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Fujisawa’s principal place of business is located at Three Parkway North, Deerfield, IL 60015.

(b) Defendant Fujisawa USA, Inc. (“Fujisawa USA”) was a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Fujisawa USA’s principal place of business was located at Three Parkway North, Deerfield, IL 60015.

48. Defendant Genentech, Inc. (“Genentech”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Genentech’s principal place of business is One DNA Way South, San Francisco, CA.

49. Defendant Genzyme Corporation (“Genzyme”) is a Massachusetts corporation engaged in the business of manufacturing and selling pharmaceuticals. Genzyme’s principal place of business is located at 500 Kendall Street, Cambridge, MA 02142.

50. Defendant Gilead Sciences, Inc., (“Gilead”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Gilead’s principal place of business is located at 333 Lakeside Drive, Foster City, CA, 94404.

51. The following two defendants are hereinafter referred to as the GSK Group:

(a) Defendant GlaxoSmithKline P.L.C. (“GSK”), created through the merger of Glaxo Wellcome, P.L.C. and SmithKlineBeecham P.L.C., is a British corporation engaged in the business of manufacturing and selling pharmaceuticals. GSK’s principal place of business is located at 980 Great West Road, Brentford, Middlesex, EN, TW8 9, U.K. Cerenex Pharmaceuticals (“Cerenex”) is a division of GSK

(b) Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline (“SmithKline”), a wholly owned subsidiary of the former SmithKlineBeecham P.L.C., is a Pennsylvania corporation engaged in the business of manufacturing and selling pharmaceuticals. SmithKline’s principal place of business is located at One Franklin Plaza, 16th and Race Streets, Philadelphia, PA 19102.

52. The following two defendants are hereinafter referred to as the Ivax Group:

(a) Defendant Ivax Corporation (“Ivax”) is a Florida (formerly Delaware) corporation engaged in the business of manufacturing and selling pharmaceuticals. Ivax’s principal place of business is located at 4400 Biscayne Blvd., Miami, FL, 33137.

(b) Defendant Ivax Pharmaceuticals Inc. (“Ivax Pharm”) (formerly Zenith Goldline Pharmaceuticals, Inc.) a wholly owned subsidiary of Ivax, is a Florida corporation

engaged in the business of manufacturing and selling pharmaceuticals. Ivax Pharm's principal place of business is located at 4400 Biscayne Blvd., Miami, FL, 33137.

53. The following five defendants are hereinafter referred to as the Johnson & Johnson Group:

(a) Defendant Johnson & Johnson ("J&J") is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. J&J's principal place of business is located at One Johnson & Johnson Plaza, New Brunswick, NJ, 08933.

(b) Defendant Janssen Pharmaceutica Products, LP ("Janssen"), a wholly owned subsidiary of J&J, is a New Jersey limited partnership engaged in the business of manufacturing and selling pharmaceuticals. Janssen's principal place of business is located at 1125 Trenton-Harbourton Road, Titusville, NJ 08560.

(c) Defendant Ortho-McNeil Pharmaceutical, Inc. ("Ortho McNeil"), a wholly owned subsidiary of J&J, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Ortho McNeil's principal place of business is located at 1000 U.S. Route 202 South, Raritan, NJ 08869.

(d) Defendant Ortho Biotech Products, LP ("Ortho Biotech"), a wholly owned subsidiary of J&J, is a New Jersey limited partnership engaged in the business of manufacturing and selling pharmaceuticals. Ortho Biotech's principal place of business is located at 700 U.S. Highway 202, Raritan, NJ 08869.

(e) Defendant McNeil-PPC, Inc. ("McNeil"), a wholly owned subsidiary of J&J, is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. McNeil's principal place of business is located at 7050 Camp Hill Road, Fort

Washington, PA 19034. McNeil Consumer & Specialty Pharmaceuticals (“McNeil Cons”) is a division of McNeil.

54. The following two defendants are hereinafter referred to as the King Group:

(a) Defendant King Pharmaceuticals, Inc. (“King”) is a Tennessee corporation in the business of manufacturing and selling pharmaceuticals. King’s principal place of business is located at 501 Fifth St., Bristol, TN 37620.

(b) Defendant Monarch Pharmaceuticals, Inc. (“Monarch”), a wholly owned subsidiary of King is a Tennessee corporation in the business of manufacturing and selling pharmaceuticals. Monarch’s principal place of business is located at 501 Fifth Street, Bristol, TN 37620. Monarch’s Altace® is marketed by Monarch and by Wyeth (another defendant herein) pursuant to the Co-Promotion Agreement entered into in June 2000.

55. Defendant MedImmune, Inc. (“MedImmune”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. MedImmune’s principal place of business is located at One MedImmune Way, Gaithersburg, MD 20878.

56. Defendant Merck & Co., Inc. (“Merck”) is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. Merck’s principal place of business is located at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100.

57. The following three defendants are hereinafter referred to as the Mylan Group:

(a) Defendant Mylan Laboratories, Inc. (“Mylan”) is a Pennsylvania corporation engaged in the business of manufacturing and selling pharmaceuticals, mainly

through its subsidiaries. Mylan's principal place of business is located at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.

(b) Defendant Mylan Pharmaceuticals, Inc. ("Mylan Pharm"), a wholly owned subsidiary of Mylan, is a West Virginia corporation engaged in the business of manufacturing and selling pharmaceuticals. Mylan Pharm's principal place of business is located at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.

(c) Defendant UDL Laboratories, Inc. ("UDL"), a wholly owned subsidiary of Mylan, is an Illinois corporation engaged in the business of manufacturing and selling pharmaceuticals. UDL's principal place of business is located at 1500 Corporate Drive, Suite 400, Canonsburg, PA 15317.

58. The following two defendants are hereinafter referred to as the Novartis Group:

(a) Defendant Novartis Pharmaceuticals Corporation ("Novartis") is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. Novartis' principal place of business is located at One Health Plaza, East Hanover, NJ 07936.

(b) Defendant Sandoz, Inc. ("Sandoz"), formerly known as Geneva Pharmaceuticals, Inc., is a wholly owned subsidiary of Novartis. Sandoz is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Sandoz's principal place of business is located at 506 Carnegie Center, Suite 400 Princeton, NJ 08540.

59. Defendant Novo Nordisk Pharmaceuticals, Inc. ("Nordisk") is a corporation engaged in the business of manufacturing and selling pharmaceuticals. Nordisk is the U.S. health care affiliate of Novo Nordisk A/S, the world's largest producer of

pharmaceuticals for endocrine disorders. Nordisk's principal place of business is located at 100 College Road West, Princeton, NJ 08540.

60. Defendant Organon Pharmaceuticals USA, Inc. ("Organon") is a Delaware corporation, a subsidiary of Akzo Nobel, NV and is engaged in the business of manufacturing and selling pharmaceuticals. Organon's principal place of business is located at 56 Livingston Ave, Roseland, NJ 07068.

61. Defendant Par Pharmaceutical, Inc. ("Par") is a New Hampshire corporation engaged in the business of manufacturing and selling pharmaceuticals. Par's principal place of business is located at One Ram Ridge Road, Spring Valley, NY 10977.

62. The following defendants are hereinafter referred to as the Pfizer Group:

a) Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Pfizer's principal place of business at 235 East 42nd Street, New York, New York.

b) Defendant Pharmacia Corporation ("Pharmacia") is a wholly-owned Pfizer subsidiary engaged in the business of manufacturing and selling pharmaceuticals. Pharmacia's principal place of business is located at 100 Route 206, North Peapack, New Jersey.

c) Defendant Agouron Pharmaceuticals, Inc. is a California corporation engaged in the business of manufacturing and selling pharmaceuticals, and a wholly owned Pfizer subsidiary. Agouron's principal place of business is located at 10777 Science Center Dr. San Diego, CA 92121-1111.

d) Defendant Greenstone, LTD is a Delaware corporation engaged in the business of manufacturing and or selling pharmaceuticals. Greenstone LTD is a wholly owned Pfizer subsidiary. Greenstone's principal place of business is located at 100 Route 206 North Peapack, NJ 07977.

63. Defendant Purdue Pharma, L.P. ("Purdue") is a pharmaceutical company engaged in the business of manufacturing and selling pharmaceuticals. Purdue's principal place of business is One Stamford Forum, 201 Tresser Boulevard, Stamford, CT.

64. Defendant Reliant Pharmaceuticals, LLC ("Reliant") is a Pennsylvania corporation engaged in the business of manufacturing and selling pharmaceuticals. Reliant's corporate headquarters is located at 110 Allen Road, Liberty Corner, NJ 07938.

65. Defendant Sanofi-Synthelabo, Inc. ("Sanofi") is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Sanofi's principal place of business is located at 90 Park Avenue, New York, NY 10016.

66. The following two defendants are hereinafter referred to as the Hoffman-LaRoche Group:

(a) Defendant Hoffman-La Roche, Inc. ("Hoffman-LaRoche") is a New Jersey corporation. Hoffman-LaRoche is the U.S. prescription drug unit of the Roche Group and is engaged in the business of manufacturing and selling pharmaceuticals. Roche's principal place of business is located at 340 Kingsland Street, Nutley, NJ 07110-1199.

(b) Defendant Roche Laboratories, Inc. ("Roche Labs"), a wholly owned subsidiary of Roche, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Roche Labs' principal place of business is located at 340 Kingsland Street, Nutley, NJ 07110-1199.

67. The following three defendants are hereinafter referred to as the Schering Group:

(a) Defendant Schering-Plough Corp. (“Schering-Plough”) is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. Schering’s principal place of business is located at 2000 Galloping Hill Rd., Kenilworth, NJ 07033.

(b) Schering Corporation (“Schering”) is a corporation organized under the laws of New Jersey with its principal offices located at 1 Giralda Farms, P.O. Box 1000, Madison, New Jersey 07940. Schering-Plough and Schering are the actual manufacturers, marketers, sellers, and/or suppliers to the products involved in this litigation and are Warrick’s actual parent(s) or shareholder(s).

(c) Defendant Warrick Pharmaceuticals Corporation (“Warrick”), a wholly owned direct subsidiary of Schering-Plough and Schering, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Warrick’s principal place of business allegedly is located at 12125 Moya Boulevard, Reno, NV 89506, however discovery in the matter styled the *State of Texas ex rel. Ven-a-Care of the Florida Keys, Inc., v. Warrick Pharmaceuticals Corp*, Schering Plough Corp, et al., No GV002327 (District Court, Travis County, Texas), led the State of Texas to conclude that Warrick’s principal offices and operations are actually in the State of New Jersey, where its direct parents Schering-Plough and Schering are located.

68. Defendant Serono, Inc. (“Serono”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Serono’s principal place of business is located at One Technology Place, Rockland, MA 02370.

69. Defendant Takeda Pharmaceuticals North America, Inc. (“Takeda”) is a corporation engaged in the business of manufacturing and selling pharmaceuticals. Takeda’s principal place of business is located at 475 Half Day Road, Suite 500, Lincolnshire, IL 60069.

70. Defendant TAP Pharmaceutical Products, Inc. (“TAP”), a joint venture between defendant Abbott and Takeda Chemical Industries, Ltd., of Osaka, Japan, is a corporation engaged in the business of manufacturing and selling pharmaceuticals. TAP’s principal place of business is located at 675 North Field Drive, Lake Forest, IL 60045.

71. Defendant Teva Pharmaceutical USA, Inc. (“Teva”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Teva’s principal place of business is located at 650 Cathill Road, Sellersville, PA, 18960.

72. Defendant UCB Pharma, Inc. (“UCB”) is the U.S. subsidiary of UCB S.A., a Belgian company. UCB’s principal business is the manufacturing, developing and marketing of pharmaceutical products. UCB’s principal place of business is in the United States at 1950 Lake Park Drive, Smyrna, Georgia 30080.

73. The following two defendants are hereinafter referred to as the Watson Group:

(a) Defendant Watson Pharmaceuticals, Inc. (“Watson”) is a Nevada corporation engaged in the business of manufacturing and selling pharmaceuticals. Watson’s principal place of business is located at 311 Bonnie Circle, Corona, CA 92880.

(b) Defendant Watson Pharma, Inc., formerly known as Schein (“Watson Pharma”), a wholly owned subsidiary of Watson since 2000, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Watson Pharma’s principal place of business is located at 311 Bonnie Circle, Corona, CA 92880.

74. Defendant Wyeth, formerly American Home Products Corp., is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Wyeth's principal place of business is located at Five Giralda Farms, Madison, NJ 07940. Wyeth-Ayerst is a division of Wyeth.

IV. ALLEGATIONS APPLICABLE TO ALL DEFENDANTS

A. THE MEDICAID STATUTORY SCHEME

75. Medicaid was established by Title XIX of the Federal Social Security Act (the "Act"), 42 U.S.C. §§ 1396 et seq. (the "Medicaid Program"). The Act mandates the establishment of minimum health and safety standards that must be met by providers and suppliers, such as defendants, participating in the Medicaid Program.

76. State participation in Medicaid is voluntary, but once a state agrees to participate, as New York has (*see* N.Y. Social Services Law § 363 *et seq.*) the state must comply with all federal statutory requirements. The Medicaid plan proposed by each state must be approved by the federal government. *See* 42 U.S.C. § 1396a(a) and (b). New York State's Medicaid plan has been expressly approved by the federal government. 42 C.F.R. § 433.32, at 79-29, 42 C.F.R. § 433.33, at 80-84.

77. New York State's Medicaid plan requires that local social service districts, such as Westchester, pay one half of the district's costs for drugs covered by Medicaid, after first deducting the federal share. N.Y. Social Services Law § 368-a. The federal share is generally 50 percent of the cost, 42 U.S.C. § 1396(d)(b), leaving the remaining 50 percent to be split equally between the State and the Westchester.

78. Federal Medicaid law requires states and localities to seek recovery of the full amount of any overcharge to the Medicaid program, including the federal and state shares of such overcharges. 42 U.S.C. § 1396a(a)(25)(A) & (B); 42 U.S.C. § 1396b(d)(3)(A). New

York law implements these federal statutory requirements by providing treble damages for any knowing overcharge of the Medicaid program, and further providing to “the local social services district or the state” a cause of action for recovery of such damages. N.Y. Soc. Serv. L. § 145-b(2). Under the New York statute, “[a]mounts collected pursuant to a judgment under this section shall be apportioned between the local social services district and the state” *Id.*

1. Initial Medicaid Payments for Drugs Are Based on AWP

79. There are approximately 65,000 different prescription drug products in the United States market, including different dosages and packagings of the same drug. Each prescription drug is assigned a National Drug Code (“NDC codes”), also known as a formulary code. The United States Food and Drug Administration publishes such codes for each of the various dosages and packagings of each drug.

80. State law provides that Medicaid will pay providers for defendants’ drugs that are “self administered,” *i.e.*, dispensed at a pharmacy, based on AWP for such drugs. N.Y. Soc. Serv. L. §367-a(9). A separate AWP is published for each drug for which there is an NDC code.

81. Medicaid is not alone in reimbursing based on AWP. It is standard practice for the federal Medicare program, other state Medicaid programs, and public and private third-party payors and individuals to reimburse for prescription drugs based upon the AWP for such drugs.

82. AWP are published and reported by non-party publishing services in printed and electronic compendia such as the Thomson’s RedBook (the “RedBook”), the American Druggist First Databank Annual Directory of Pharmaceuticals, and Essential Directory of Pharmaceuticals (the “Blue Book”), and Medi-Span’s Master Drug Database.

These publishers report AWP based directly on wholesale price information provided by defendants. Defendants report to the publishers either an actual AWP for their drugs or other wholesale pricing information, *e.g.*, wholesale list prices, wholesale acquisition costs (“WACs”), or direct prices, which the publishers then convert to the reported AWP. In all cases, the AWP is established based on information provided by the drug manufacturer.

83. At all times relevant hereto, N.Y. Soc. Serv. L. § 367-a(9)(b) has set New York’s Medicaid pharmacy reimbursement rate. At all times relevant hereto such reimbursement rate has been based on AWP.

84. For multi-source or generic drugs that have at least three suppliers, the Center for Medicare and Medicaid Services (“CMMS”) generally establishes federal upper limits (“FULs”), defined as 150% of the lowest reported AWP. 42 C.F.R. § 447.332. However, at times CMMS delays in calculating the FUL, and because the FUL must be recalculated periodically, even drugs that do have a FUL in one year may not have one the next year. Pursuant to New York State Social Services Law, at all times relevant hereto, Medicaid reimbursement for drugs that do have a FUL has been at the FUL. N.Y. Soc. Serv. L. § 367-a(9)(b)(i).

85. For all other drugs – *i.e.*, for brand name prescription drugs or for multiple source prescription drugs for which no FUL has been set – prior to the 2004 statutory amendment described below, New York State law provided reimbursement at the “estimated acquisition cost,” which the statute defined as AWP minus 10% (prior to May 15, 2003) or AWP minus 12% (from May 15, 2003 to April 1, 2004). N.Y. Soc. Serv. L. § 367-a(9)(b)(ii)⁵;

⁵ The alternative measure of reimbursement for brand name drugs set forth in subsection (ii), the “usual and customary price charged to the general public,” is not used because the necessary data are not available. This alternative measure has been retained in the 2004 amendment.

see N.Y. Laws 2003, Ch. 62, Part Z2 (decreasing reimbursement from AWP minus 10% to AWP minus 12).

86. In 2004, N.Y. Soc. Serv. L. § 367-a(9) was amended, effective April 1, 2004, to provide that brand name drugs are reimbursed at the rate of AWP minus 12.75%⁶ and generic drugs for which no FUL has been established are reimbursed at AWP minus 16% or at a maximum price determined by the New York State Commissioner of Health using “a similar methodology as that utilized by the Centers for Medicare and Medicaid Services in establishing the federal upper payment limit.” N.Y. Soc. Serv. L. § 367-a(9)(e) and Laws 2004, Ch. 58, Part C, §36.

87. In addition, New York law has at all relevant times provided for a dispensing fee of between \$3.50 to \$4.50 to be added to all reimbursements. N.Y. Soc. Serv. L. § 367-a(9)(d).

88. The pricing and reimbursement data set forth in this Complaint reflect Westchester’s 2002 Medicaid Pharmacy costs, based on the then-applicable formula for Medicaid reimbursement of AWP minus 10 percent.

89. States rely on AWP in part because defendants keep accurate pricing information secret. Even at the time when the Medicaid rebate provision was enacted, the manufacturers made sure that pricing information would not be disclosed to the states. As Representative Henry Waxman explained during the December 2004 House Subcommittee hearings,

the drug industry was powerful, and they succeeded in securing a provision in the basic legislation that kept the Best Price and the AMP information a secret. Can you imagine that? The federal

⁶ The 2004 amendment creates one exception to the reimbursement formula: “specialized HIV pharmacies”, as defined by N.Y. Soc. Serv. L. §367-a(9)(f), are reimbursed for all drugs without FULs at AWP minus 12%. N.Y. Soc. Serv. L. §367-a(9)(b)(ii).

government knew this information, but we kept it a secret from the states. This has proved to be a costly error. Without this crucial piece of information, states who were, after all, responsible establishing the reimbursement rate for prescription drugs could not set their reimbursement rates appropriately. As a result, [the states] continued to rely on the average wholesale price minus the arbitrary amount because they did not have the information needed to set a more appropriate reimbursement rate.

Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much: Hearing Before the House Subcomm. on Oversight and Investigations, 108th Cong. Tr. 23 (2004) (statement of Cal. Harry Waxman, Member, House Subcomm. on Oversight and Investigations).

90. The federal government has emphasized the importance of accurate AWP. In its April 2003 report, “Compliance Program Guidance for Pharmaceutical Manufacturers,” the HHS OIG reaffirmed that the “government sets reimbursement with the expectation that the data provided are complete and accurate.” The OIG made clear that the AWP must be a meaningful figure that is not artificially inflated:

Where appropriate, manufacturers’ reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

Off. of Inspector Gen., Dep’t of Health and Human Services, Compliance Program Guidance for Pharmaceutical Manufacturers, at 12 (2003)

91. The OIG rejected the notion that purposeful AWP manipulation was a lawful practice:

The “spread” is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the “spread,” it controls its customer’s profit.

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at “95 percent of average wholesale price.” 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers’ profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller’s immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. **In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the “spread” to induce customers to purchase its product.**

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. **The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute.** Active marketing of the spread includes, for example, sales representatives

promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

Id. at 26-27 (2003) [emphases added].

2. Medicaid Rebates Are Based on Best Price, AMP and the CPI

92. The second component of the price that Medicaid pays for prescription drugs is determined by the federally mandated rebate provision. Under the Medicaid rebate provision, 42 U.S.C. § 1396r-8, a manufacturer of a drug that wishes to have its products paid for by Medicaid must enter into a rebate agreement with the Secretary of Health and Human Services.

93. The rebate for brand-name drugs (defined as “single source drugs” or “innovator multiple source drugs”) is the difference between the AMP and the Best Price, or 15% of the AMP, whichever is greater. 42 U.S.C. §§ 1396r-8(c)(1) – (2); N.Y. Soc. Serv. L. § 367 (a)(7)(d). Thus, the lower the Best Price, the greater the rebate.

94. The statute requires each manufacturer of single source or brand name innovator drug to report to Medicaid its Best Price and its AMP and to pay rebates to state Medicaid programs based on its own accurate determination of Best Price and AMP. 42 U.S.C. § 1396r-8(b)(1)(A).⁷

95. Where the cost of a drug has outpaced the increase in the consumer price index over a period of time, the Medicaid rebate provision, 42 U.S.C. § 1396r-8(c)(2), requires each drug manufacturer to pay an additional rebate. 42 U.S.C. § 1396r-8(c)(2),

96. The Medicaid rebate provision contains precise specifications concerning how the Best Price is to be calculated. It defines Best Price as “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health

⁷ The rebate for other drugs is 11.1% of AMP. 42 U.S.C. § 1396r-8(c)(3); N.Y. Soc. Serv. L. § 367 (a)(7)(d).

maintenance organization, non-profit entity or governmental entity in the United States,” with certain enumerated exceptions. 42 U.S.C. § 1396r-8(c)(1)(C)(i).

97. After excluding the prices given to certain drug purchasers from the definition and including others explicitly, the Statute states:

the term “Best Price” –

- (I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);
- (II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and
- (III) shall not take into account prices that are merely nominal in amount.

42 U.S.C. § 1396r-8(c)(1)(C)(ii).

98. AMP is defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts. 42 U.S.C. § 1396r-8(k)(1).

99. Congress passed the rebate provision expressly to help reduce state Medicaid drug expenditures. H.R. Rep. No. 101-881 at 96-8 (1990), U.S.C.C.A.N. 1990, 2017, 2108-2110.

100. New York Statute Law § 367-a(7)(d) expressly incorporates the rebate requirements of 42 U.S.C. § 1396r-8 and provides that where a manufacturer has entered into a rebate agreement, as outlined above, reimbursement to the New York State Medicaid program shall be made only pursuant to the terms of that rebate agreement.

101. New York Social Service Law also requires that the State return to the local social service district, such as Westchester, the local district’s *pro rata* share of any rebate received. New York’s Medicaid plan was approved expressly by the federal government.

Thus, Westchester and all other local social service districts are within the class of entities for whose benefit the Medicaid rebate provision was enacted.

102. To effectuate the purpose of the statute, manufacturers are required to report their Best Prices and AMPs to the Secretary of HHS, who is required to keep the information confidential. 42 U.S.C. §§ 1396r-8(b)(3)(A), (D).

103. The states are required to report to the manufacturers, as well as to HHS, the “information on the total number of units of each dosage strength and package size of each covered outpatient drug . . . for which payment was made under the plan during the period.” 42 U.S.C. § 1396r-8(b)(2).

104. The Secretary calculates the rebates according to the statutory formulas and reports to each state a Unit Rebate Amount, which is “the amount calculated by the Health Care Financing Administration to which the Medicaid utilization information may be applied by states in invoicing the Manufacturer for the rebate payment due.” The rebate then is paid to the state Medicaid program by the defendant drug manufacturer.

105. States thus are provided with Unit Rebate Amounts, not the AMPs or Best Prices. See Brief of the United States as *Amicus Curiae* filed in *In re: Pharmaceutical Industry Average Wholesale Price Litigation* (No. 01-CV-12257-PBS) (MDL No. 1456 D. Mass.) at 15 (arguing that the federal rebate provision, 42 U.S.C. § 1396r-8, does not preempt state law fraud claims based on fraudulent reporting of rebate data) (hereinafter “*Amicus* brief”). Like HHS, the States are also required to keep confidential the rebate-related information that they receive. 42 U.S.C. § 1396r-8(b)(3)(D).

106. While the Secretary provides supplemental guidance to manufacturers regarding their Best Price obligations through program releases and training guides, the Secretary relies entirely on the manufacturers for Best Price and AMP data.

107. The Model Rebate Agreements follow the statute in expressly providing that the manufacturers have ultimate responsibility for the calculation of the rebate:

A State may, at its option, compute the total rebate anticipated, based on its own records, *but it shall remain the responsibility of the labeler* to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

Model Rebate Agreement, annexed hereto and incorporated herein, at I(n).

108. Each defendant and the Secretary of Health and Human Services “on behalf of the Department of Health and all States and the District of Columbia . . . which have a Medicaid State Plan approved under 42 U.S.C. § 1396a” has executed a Rebate Agreement that is in all material respects identical to the Model Rebate Agreement (Exhibit E).

109. While the Model Rebate Agreement largely tracks the statutory rebate provision, it also goes beyond it in some respects. The Model Rebate Agreement defines Best Price as “the lowest price at which the manufacturer sells . . .to any purchaser in the United States in any pricing structure.” Model Rebate Agreement, at I(d).

110. The Model Rebate Agreement provides also that “[f]or bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement.” *Id.*, at I(d).

111. Bundled discounts are defined in the Model Rebate Agreement as “the packaging of drugs of different types where the condition of rebate or discount is that more than one type of drug is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.” *Id.* at I(e).

112. The Model Rebate Agreement defines “State Medicaid Agency” as “the agency designated by a state under Section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.” Model Rebate Agreement at I(bb).

113. The Medicaid statute also provides that “the State or local agency administering such plan will take all reasonable measures to ascertain the legal liability of third parties for any overcharges and submit to the Secretary of Health and Human Services a plan for pursuing such claims.” 42 U.S.C. § 1396a (a)(25)(A).

114. Westchester is a local social services district under State law. N.Y. Soc. Serv. L. §§ 55, 61-62. Within the State scheme, and subject to State supervision, it plays a major role in administering the Medicaid program for Westchester residents. It has its own fraud and overpayments unit, determines eligibility, and performs other important functions.

115. In any case where such a legal liability is found to exist and where the amount of reimbursement the State can reasonably expect to recover exceeds the costs of such recovery, the State or local agency will seek reimbursement for such reimbursement to the extent of such legal liability. 42 U.S.C. 1396a (a)(25)(B).

116. Under the Medicaid rebate provision, any manufacturer that knowingly provides false information “is subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information.” “[S]uch civil money penalties are in addition to other penalties as may be prescribed by law.” 42 U.S.C. § 1396r-8(c)(ii) (emphasis added).

117. New York Social Services Law § 145-b expressly provides for other penalties where false information, such as inaccurate Best Prices, is provided and Medicaid overpays as a result. Section 145-b expressly provides further that a local social services

district has “a right to recover civil damages equal to three times the amount which any figure is falsely overstated. . .”

118. In his *Amicus* brief, at 8, the Secretary of HHS wrote:

States obviously have a direct and compelling interest in accurate Best Price reporting and the rebate program, which helps to reduce the costs the states themselves incurred for drugs purchased by Medicaid patients. It is within their [the state’s] statutory authority to investigate and prosecute Medicaid best price violations as alleged in this case.

Because Westchester, like the State, is a Medicaid payor, it also has a direct and compelling interest in accurate Best Price reporting.

B. DEFENDANTS’ FRAUDULENT CONDUCT

1. Intentionally False and Inflated AWP

119. At all times relevant hereto, each defendant has intentionally reported, or caused to be reported, to industry publications wholesale pricing information that it knew to be false and inflated, with the intention and knowledge that the published information would be relied upon by Medicaid, Medicare and private payors for calculating drug payments and reimbursements. Indeed, defendants’ own marketing materials make plain that they market their products based on AWP spread.

120. Exhibit A attached hereto shows Westchester’s expenditures during the calendar year 2002 for each of the drugs at issue herein. Exhibit A also notes which of defendants’ drugs for which Westchester seeks relief are also at issue in other proceedings in this MDL.

121. Exhibit B to this Complaint sets forth the reported AWPs for certain of defendants’ brand name drugs and the estimated amount of overcharge to Westchester during the year 2002. According to HHS and industry experts, the actual wholesale prices paid for

brand name drugs by prescription drug wholesalers are on average 27% lower than average retail prices. The estimated overcharges in Exhibit B are based on the assumption that the true average wholesale price for each drug is approximately equal to the retail price minus at least 27%. *See, e.g., J.R. Graham & B. Robson, Prescription Drug Prices in Canada and the United States: Part 1: A Comparative Survey*, Public Policy Sources, Volume #42 (Aug. 23, 2000)

122. Reducing retail prices by 27% to obtain an estimated wholesale price for each drug, it can be determined that the AWP's reported by defendants are routinely and significantly higher than actual wholesale prices. These estimates show that the reported AWP's for brand name drugs are on average 20 percent above true average wholesale prices. This confirms the findings of numerous governmental investigations, studies and settlements described herein, including the December 2004 House Energy and Commerce hearings. Thus, even a 10 or 12 or 12.75 percent discount off AWP, as New York's Medicaid law mandates for brand-name drugs, does not eliminate the damage resulting from defendants' submission of false wholesale price information.

123. For generic drugs, the price inflation and the corresponding overpayments tend to be far higher than the brand name estimates in Exhibit B. Congressional and other federal investigations have concluded that defendants' reporting of intentionally false and inflated AWP's is greatest in the generic or multi-source drug arena. This is hardly surprising, because competition among manufacturers – and therefore, the fight for market share – is greatest in this arena.

124. Generic or multi-source drug manufacturers are aware of the AWP's reported by their competitors and of the actual sales price of their generic competitors' products. Generic drug manufacturers manipulate their own AWP's in order to gain or maintain

a competitive advantage in the market for their generic products. The effect is what has been called a “leap frogging” where all AWP’s for a particular generic spiral upwards as companies attempt to create spread.

125. The natural and expected result is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP exceeding actual costs by over 50,000%. In the case of Fluoxetine, described by the *Wall Street Journal* and recited above, the Westchester Medicaid program was overcharged at least between 56% and 95% (depending on the dosage and packaging) for each pill as a result of a fraudulently inflated AWP. A few other examples collected by the DOJ are set forth below:

| Defendant | Multi-source Drug | RedBook AWP | DOJ Determined Actual AWP | Percentage Spread |
|----------------------|---------------------|-------------|---------------------------|-------------------|
| Baxter | Dextrose | \$ 928.51 | \$ 2.25 | 41,167% |
| Baxter | Sodium Chloride | \$ 928.51 | \$ 1.71 | 54,199% |
| Boehringer* | Leucovorin Calcium | \$ 184.40 | \$ 2.76 | 6,581% |
| B. Braun | Sodium Chloride | \$ 11.33 | \$ 1.49 | 660% |
| Bristol-Myers Group* | Etoposide (Vepesid) | \$ 136.49 | \$ 34.30 | 298% |
| Dey* | Albuterol Sulfate** | \$ 30.25 | \$ 9.17 | 230% |
| Immunex* | Leucovorin Calcium | \$ 137.94 | \$ 14.58 | 846% |
| Pharmacia | Etoposide | \$ 157.65 | \$ 9.47 | 1,565% |
| Sicor Group | Tobramycin Sulfate | \$ 342.19 | \$ 6.98 | 4,802% |
| Watson* | Vancomycin HCL | \$ 70.00 | \$ 3.84 | 1,567% |

* Defendants herein.

**Drugs herein.

126. Defendants’ own marketing documents make clear that they market spread and profitability based on reimbursement whether their products are single or multi-source. Defendants market spread for their drugs even when they are competing with over-the-counter

alternatives. Thus, the motivation to improperly inflate AWP obtains regardless of whether a drug is brand name, single source, multi-source or generic.

127. In its complaint concerning certain of the same defendants and underlying fraud, the Montana Attorney General cites an industry consultant on this point as follows:

This situation is more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by substantially inflating their published AWP's. . . . [T]he system allows a retailer to acquire a drug at a low cost, \$2.50 per 100 tablets, for example, while relying on a published AWP (\$20.00 or more) for its own pricing. It is not uncommon that the \$25.00 retail price for a generic drug renders a gross profit well above \$20.00 for the retailer. It is also common for the AWP of a generic product to remain stable while the actual selling price declines It is obvious that AWP is not an accurate measure of the prices manufacturers charge. It must also be noted that not all generic products will be priced similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AWP. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing decisions and an artificially high AWP provides the retailer with greater profits.

128. On information and belief, each defendant has reported false and inflated AWP's or other wholesale price information on which AWP's are based in years prior and subsequent to 2002, resulting in comparable damage to Westchester for all covered drugs manufactured by it.

129. These reported prices were far in excess of the amounts that the manufacturers charged to wholesalers or providers, indeed higher than any purchase price paid by any participant in the drug distribution chain. In fact, AWP's are completely fictitious prices that no one ever actually pays. They are created out of thin air for the sole purpose of creating a marketable spread as described herein.

130. These facts are confirmed by investigations by Congress, the General Accounting Office (“GAO”) and the HHS OIG, and by litigations by the Department of Justice (“DOJ”), various state Attorneys General and U.S. Attorneys, as detailed below.

131. The HHS OIG has emphasized that “manufacturers’ reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers.”

132. Defendants report wholesale price information that they know does not comply with the HHS OIG’s guidelines, in that they do not account for routine prompt pay discounts, bundled discounts, chargebacks, rebates, free samples and other discounts and inducements they offer to wholesalers, chain pharmacies, group purchasing organizations, pharmacists and other distributors who are in a position to increase sales of defendants’ products.

133. For example, defendants regularly pay “chargebacks” that are not accounted for in their reported AWP. Chargebacks are payments by defendants to drug wholesalers to compensate the wholesaler for its sales of defendants’ drugs to an indirect purchaser to whom the manufacturer has agreed to sell its drugs at a deep discount.

134. Defendants also routinely pay two percent prompt pay discounts to wholesalers that are not accounted for in their reported AWP. Prompt pay discounts are given when the purchaser pays the drug manufacturer within a prescribed period of time. Wholesalers uniformly avail themselves of prompt pay discounts. Other credits, rebates,

hidden discounts and financial incentives likewise are routinely provided and not included in the AWP or other wholesale pricing data reported by defendants.

135. Defendants know that AWP is inflated, yet nevertheless report or cause the AWP to be issued. Defendants at all times relevant could report accurate average wholesale prices based on good faith and reasonable estimates utilizing the pricing and transactional information defendants maintain in conducting their ordinary business affairs.

136. By increasing the spread on its drugs, each defendant seeks to influence drug-selecting entities such as physicians, pharmacies, PBMs and/or others in the drug distribution chain to increase their purchases of its drugs. Defendants engage in this purposeful manipulation for the sole and express purpose of creating demand for their products. Manufacturers market the spread to PBMs to gain inclusion into a PBM's formulary, and to wholesalers and pharmacists to be the exclusive supplier of a multi-source drug or to otherwise incentivize them to distribute defendants' products. PBMs and pharmacists benefit by pocketing the difference between the reported AWP and the actual cost they pay for the drug.

137. The success of this scheme is well documented. As one example, Martha McNeill, the head of Texas' Medicaid drug program, testified that when Texas cut Warrick's inhaler reimbursement from \$16.79 to \$6.26, Warrick's Medicaid market share for the inhaler dropped from 71% to 42% in less than 2 years. Andrew Caffrey, Scott Hensley & Russell Gold, *States Go to Court in Bid to Rein in Price of Medicine*, WALL ST. J., May 21, 2002, at A1.

2. The Role of PBMs in the AWP Scheme

138. PBMs specialize in the administration and management of prescription benefit programs. Their clients include HMOs, employers, preferred provider organizations and other health insurers. Three PBMs, AdvancePCS/Caremark, Express Scripts and Medco

Health, together control eighty percent of the PBM market and supply the prescription drugs of approximately 210 million people in the United States. *See* David A. Balto, Competitive Concerns and Price Transparency in the PBM Market, UPDATE, September/October 2003, at 35.

139. PBMs operate in two primary businesses: First, PBMs contract with pharmaceutical manufacturers, retail pharmacies, and health plans to decide which drugs should be included in formularies, to bill health plans for prescription drug payments on behalf of plan participants, and to pay the pharmacies. Second, PBMs operate their own proprietary mail order pharmacies.

140. PBMs' historic business model was to procure drugs for their health plan client in exchange for administrative fees. According to the Wall Street Journal, "[t]raditionally, PBMs received only modest administrative fees for arranging prescriptions at cost." Barbara Martinez, Rx for Margins: Hired to Cut Costs, Firms Find Profits Inn Generic Drugs, Pharmacy-Benefit Managers Can Take Huge Markups And Still Offer 'Discounts,' Making \$170 on just 90 Pills, WSJ, March 31, 2003, at A1.

141. This model has changed in recent years such that PBMs now are "increasingly . . . reducing those fees and trying to take advantage of the "spread" between pharmacy prices and what corporate and government clients pay. Express Scripts say most of its contracts now include spread pricing." *Id.*

142. The following is an example of a typical PBM transaction and a description of the contracts that underpin it. A health plan participant is prescribed a drug by a physician. The participant fills the prescription at a PBM-approved pharmacist, paying only the co-pay. The pharmacist buys the drug either directly from the manufacturer or from a

wholesaler. The pharmacist then bills the PBM for the drugs it sells to the patient. The PBM has a contract with the retail pharmacy to pay a price at a certain discount off AWP, *e.g.*, AWP minus 15%. The PBM in turn bills the health plan for this drug. However, the PBM has a separate contract with the health plan, entitling it to payment at a different, higher rate, *e.g.*, AWP minus 10%. Thus, in addition to any administrative fee the PBM receives, the PBM receives the spread between the contractual payment it receives from the health plan and the contractual payment it makes to the pharmacist. Furthermore, if the PBM operates its own mail-order pharmacy that health plan members are required to use, the PBM reaps the pharmacist's share of the spread as well.

143. In the Introduction to this Complaint, plaintiff set forth an example of how PBMs and pharmacists profit from the spread in the case of Fluoxetine.

144. PBMs select their formularies based on the profits they can make, including the spread between actual price and AWP, and taking into account rebates, discounts, chargebacks and other incentives that the manufacturers provide:

PBMs develop relationships with manufacturers that provide lower pricing (through rebates) when a particular drug is on the formulary.... In general, the level of rebates increases if the PBM increases a greater market share for a drug within a defined class of prescriptions with similar therapeutic effects.

Providing Prescription Drug Coverage Through Medicare: The Role of Pharmacy Benefit Managers, U.S. Senate Committee on Finance (Mar. 29, 2000), at 4-5 found at <http://www.senate.gov/~finance/3-29mcca.htm>.

145. Defendants know and understand that third-party payors and PBMs rely on the *RedBook* and other compendia to determine the AWP of the covered drugs, both brand name and generic. Because defendants control the published AWP, defendants know and understand that they can manipulate the providers' and PBMs' profits, gained at the expense of

third-party payors, including Westchester, to incentivize these providers and PBMs to prescribe their drugs and/or to include their drugs in a drug formulary by inflating the AWP.

146. Because the PBMs consider the contracting relationship with retail pharmacies to be confidential, health plans are never informed of the reimbursement amount to pharmacies. Nor are they informed of the actual prices that pharmacies pay for the drugs.⁸

3. Failure to Report Best Prices and Pay Proper Rebates

147. At all times relevant hereto, each defendant executed a Rebate Agreement in which it promised to comply with its contractual terms and with the requirements of the Medicaid rebate provision. 42 U.S.C. § 1396-r-8.

148. At all times relevant hereto, each defendant knew that the purpose of the rebate agreements it executed was to pass on Medicaid pharmacy cost savings to the State of New York and to its local social service districts, including Westchester.

149. At all relevant times hereto, each defendant knowingly calculated its Best Prices excluding factors that it was statutorily and/or contractually required to include, resulting in an rebates that were less than required.

150. The same routine discounts, rebates, free samples and other inducements offered to providers but excluded in setting AWP are also excluded from defendants' calculations of Best Price. These include chargebacks, two percent prompt pay discounts, free samples distributed by sales representatives, and other credits, rebates, and hidden discounts and financial incentives.

151. In addition, defendants routinely bundle deeply discounted or free drugs with other drugs. The Model Rebate Agreement executed by every defendant herein expressly

⁸ The FTC issued a public notice on March 26, 2004 that Congress had requested that they conduct a study into possible conflicts of interest between PBMs and the group health plans to which they provide services. *See* <http://www.ftc.gov/os/2004/03/040326pnpbm.pdf>.

provides that for bundled sales the discount must be allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. Defendants do not properly allocate bundled discounts when calculating Best Price.

152. Certain defendants also engage in re-labeling schemes to avoid reporting Best Price. Federal law expressly prohibits this practice. 42 U.S.C. § 1396r-8(c)(ii). For example, in 2003, two defendants herein, Bayer and GSK, agreed to pay \$344 million to resolve allegations that they engaged in health care fraud against state programs by failing to report their Best Price for certain drugs. In their wrongful scheme, known as “lick and stick,” they sold drugs to Kaiser Permanente Medical Care Program (the nation’s largest HMO) at deep discounts, but avoided including these discounts in their Best Price calculations by re-labeling the products with new NDC codes before sale.

153. As described below, the HHS OIG has documented that such repackaging schemes are widespread. OIG, Medicaid Drug Rebates – Sales To Repackagers Excluded From Best Price Determinations, at 1, 4 (March 2001).

154. Upon information and belief, each of the defendant pharmaceutical companies has also utilized an array of other inducements to stimulate sales of their drugs. These inducements, including educational grants, volume discounts, and rebates or free goods, were designed to result in a lower net cost to the purchaser while concealing the actual cost price beneath a high invoice price. A product invoiced at \$100 for ten units of a drug might really only cost the purchaser one-half that amount. If one assumes a subsequent shipment of an additional ten units at no charge, or a “grant,” “rebate” or “credit memo” in the amount of \$50, the transaction would truly cost just \$5 per unit net. Through all these off-invoice means, drug purchasers are provided the substantial discounts that induce their patronage while

maintaining the fiction of a higher invoice price – the price that corresponds to reported AWP's and inflated reimbursement from Medicaid.

155. As explained below, certain defendants also are under investigation for abusing the nominal price exception to Best Price reporting, created by Congress as a public policy exception to encourage drug manufacturers to continue to sell drugs at nominal prices to entities serving the public good, without the manufacturer having to pay increased rebates because of those sales. The exception allows drug companies to exclude from their Best Price calculations drugs with prices less than 10% of AMP. 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(III).

V. GOVERNMENT INVESTIGATIONS

156. DOJ, GAO, HHS OIG, and a number of Congressional and Senate committees have investigated and are continuing to investigate defendants for questionable practices regarding the reporting of wholesale pricing information, Best Price, and other non-compliance with Medicaid rebate provision.

157. The House Committee on Energy and Commerce is conducting an investigation into pharmaceutical reimbursements and rebates under Medicaid. On June 26, 2003, Chairman Billy Tauzin (R-La.) and Oversight and Investigations Subcommittee Chairman James Greenwood (R-PA) wrote as follows to 26 drug companies, including many defendants herein:⁹

The Committee on Energy and Commerce is conducting an investigation into pharmaceutical reimbursements and rebates under Medicaid. This inquiry builds upon the earlier work by this Committee on the relationship between the drug pricing practices of certain pharmaceutical companies and reimbursement rates under the Medicare program. In that investigation, the Committee

⁹ The targeted companies include defendants Abbott Labs; Alpharma; Aventis Pharmaceuticals; Barr Labs; Bristol Myers; Dey; Ethex; Eli Lilly; Geneva; GlaxoSmithKline; IVAX; Johnson & Johnson; Mylan Pharmaceuticals; Par Pharmaceuticals; Pfizer, Inc.; Pharmacia Corp.; Purepac; Roche; Roxane; Schering-Plough; TEVA; UDL Labs; Warrick Pharmaceuticals; and Watson.

uncovered significant discrepancies between what some pharmaceutical companies charged providers for certain drugs and what Medicare then reimbursed those providers for dispensing those drugs. This price difference resulted in profit incentives for providers to use the drugs of specific companies as well as higher costs to the Medicare system and the patients it serves. For example, we learned that one manufacturer sold a chemotherapy drug to a health care provider for \$7.50, when the reported price for Medicare was \$740. The taxpayer therefore reimbursed the doctor almost \$600 for dispensing the drug and the cancer patient had a \$148 co-payment. Such practices are unacceptable in the view of the Committee, which is why we are in the process of moving legislation to address these abuses.

The Committee has similar concerns regarding drug prices in Medicaid, which has a substantially larger pharmaceutical benefit than Medicare.

House Committee on Energy and Commerce, June 26, 2003 Press Release, "Tauzin, Greenwood Expand Medicaid Fraud Investigation."

158. The letter requests extensive and specific detail about the subject companies' sales, AWP, AMPs, and WACs, and their records relating to calculation of Best Prices and their use of the nominal price exception.

159. This investigation is continuing. At a hearing on December 7, 2004, Chairman Joe Barton noted the huge inflation of the prices paid by Medicaid, particularly for generic drugs. *Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much: Hearing Before the House Subcomm. on Oversight and Investigations*, 108th Cong. Tr. 5 (2004) (statement of Joe Barton, Chairman, House Subcomm. on Oversight and Investigations). Defendant Dey's chief financial officer testified as follows:

Why doesn't Dey lower its AWP on generic drugs? The simple answer is that given the system that now exists our customers won't buy from us if we lower our AWP.

Id. at Tr. 117-118 (statement of Pamela Marrs, Senior Vice President & CFO, Dey, Inc.).

Similarly, the Senior Product Manager for defendant Roxane Laboratories testified that no one

would buy their product if the AWP was too low. *Id.* Tr. 134 (Statement of Leslie Paoletti, Roxane Laboratories, Inc.)

160. Many of the drugs under Congressional scrutiny, including Albuterol, Buspirone, Fluoxetine, Buspar, Celebrex, and Zyprexa, are drugs for which Westchester's Medicaid Program spends large sums. *See* Exhibit A.

161. On April 29, 2004, the Senate Finance Committee sent letters to 19 drug companies¹⁰ focusing on whether those companies exploited the nominal price exception. The Committee wrote:

We understand that some drug manufacturers may be using the Nominal Price Exception as part of their commercial pricing practices. These practices could undermine the purposes of the Medicaid Best Price policy and may be costing taxpayers hundreds of millions of dollars through reduced Medicaid rebates.

Senate Finance Committee Press Release, dated April 29, 2004, "Grassley, Baucus Ask Drug Manufacturers Question About How They Price Drugs For Medicaid."

162. The House and Senate Medicaid investigations described above follow comparable investigations regarding Medicare in 2000 – 2001. Congressman Pete Stark (D-Ca.) chaired that investigation.

163. In a letter dated September 28, 2000, Congressman Stark wrote to the president of the Pharmaceutical Research and Manufacturers of America ("PhRMA"), of which most of the Defendants are members, as follows:

Drug company deception costs federal and state governments, private insurers and others billions of dollars per year in excessive drug costs. This corruptive scheme is perverting the financial

¹⁰ Target companies include defendants GlaxoSmithKline, Johnson & Johnson, Merck & Co., Inc., AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Novartis Pharmaceuticals Corporation, Amgen, Inc., Wyeth Pharmaceuticals, Eli Lilly & Company, Aventis Pharmaceuticals, Inc., Abbott Laboratories, Hoffman-La Roche Inc., TAP Pharmaceutical Products Inc., Schering-Plough Corporation, Boehringer Ingelheim Pharmaceuticals, Inc., Forest Pharmaceuticals, Inc., Sanofi-Synthelabo and Eisai, Inc.

integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare's current limited drug benefit. Furthermore, these deceptive, unlawful practices have a devastating financial impact upon the states' Medicare Program. . . .

The evidence I have obtained indicates that at least some of your members have knowingly and deliberately falsely inflated their representations of the average wholesale price ("AWP"), wholesaler acquisition cost ("WAC") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The evidence clearly establishes and exposes the drug manufacturers themselves that were the direct and sometimes indirect sources of the fraudulent misrepresentation of prices. Moreover, this unscrupulous "cartel" of companies has gone to extreme lengths to "mask" their drugs' true prices and their fraudulent conduct from federal and state authorities. I have learned that the difference between the falsely inflated representations of AWP and WAC versus the true prices providers are paying is regularly referred to in your industry as "the spread." . . .

The evidence is overwhelming that this "spread" did not occur accidentally but is the product of conscious and fully informed business decisions by certain PhRMA members. . . .

September 28, 2000 letter from House Committee on Ways and Means, Subcommittee on Health, to Alan F. Holmer, President, Pharmaceutical Research and Manufacturers of America, Washington, D.C. Congressional Record, Extension of Remarks at E1622.

164. Congressman Stark came to the following five "shocking conclusions":

First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers.

Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.

Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded health care programs to expend scarce tax dollars in order to arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.

Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians’ medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.

Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

Id. E1623-24

165. In a letter to Abbott dated October 31, 2000, Congressman Stark wrote:

You should by now be aware of Congressional investigations revealing that [your company] has for many years reported and published inflated and misleading data and has engaged in other deceptive business practices. This letter is a call for your company to immediately cease overcharging taxpayers and jeopardizing public health

The price manipulation scheme is executed through [your company’s] inflated representations of average wholesale price (AWP) and direct price (“DP”) which are utilized by the Medicare and Medicaid Programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is regularly referred to in your industry as “the spread.” The evidence amassed by Congress clearly shows that [your company] has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that [your company] manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims

Based on the evidence collected, [your company] should make arrangements to compensate taxpayers for the financial injury caused to federally funded programs. Any refusal to accept responsibility will most certainly be indicative of the need for Congress to control drug prices. If we cannot rely upon drug companies to make honest and truthful representations about their

prices, then Congress will be left with no alternative but to take decisive action to protect the public.

October 31, 2000 letter from Hon. Fortney Pete Stark of California to Miles White, Chief Executive Officer, Abbott Laboratories, Abbott Park, Illinois. Congressional Record, October 31, 2000, at E2037-38.

166. The investigation led by Congressman Stark concluded that defendants employed a number of financial inducements to stimulate the sales of their drugs at the expense of both Medicare and Medicaid. Such inducements include the practices described herein, i.e., volume discounts, rebates, off-invoice pricing and free goods designed to lower the net cost to the purchaser while keeping high the cost of the drug to government programs:

Some drug companies have also utilized a large array of other impermissible inducements to stimulate sales of their drugs. These inducements, including bogus “educational grants”, volume discounts, rebates or free goods, were designed to result in a lower net cost to the purchaser while concealing the actual cost price beneath a high invoice price. A product invoiced at \$100 for ten units of a drug item might really only cost the purchaser half that amount. Given, for instance, a subsequent shipment of an additional ten units at no charge, or a “grant”, “rebate” or “credit memo” in the amount of \$50, the transaction would truly cost a net of only \$5.00 per unit. Through all these “off-invoice” means, drug purchasers were provided the substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price-the price that corresponded to reported AWP’s and inflated reimbursement . . .

Congressional Record, Sept. 28, 2000, at E1623.

167. Congressman Stark provided numerous examples of the manipulation of AWP, based on documents he had obtained from defendants:

(a) In the 2000 edition of the *RedBook*, Bristol-Myers reported an AWP of \$1,296.64 for one 20 mg/ml, 50 ml vial of Vepesid (Etoposide) for injection, while selling the exact same drug in the same quantity to a group purchasing organization for \$70. This

represents a spread between Bristol Myers' falsely inflated AWP and the real price of \$1,226.64. Congressional Record, September 28, 2000 at E1623.

(b) Effective January 10, 1995, defendant Glaxo increased the AWP for Zofran by 8.5 percent while simultaneously giving a 14 percent rebate to providers that more than offset the price increase to Medicaid. The net effect of these adjustments was to increase the amount of reimbursements available to providers from payors whose reimbursement is based on AWP. Because the net price paid to Glaxo for Zofran actually went down, the increase in the AWP did not increase revenue per unit to Glaxo. This adjustment demonstrates an intent to induce providers to purchase Zofran by enabling them to receive increased reimbursement from Medicaid and other third party payors. *Id.* at E1622.

(c) Abbott's Amikacin, used to treat an infection that HIV positive people are susceptible to, had an AWP of \$54.56. The actual Best Price was \$6.75. Abbott's Vancomycin, an antibiotic used to treat intestinal infections, had an AWP of \$68.77 as of April 2000. DOJ adjusted it to \$8.14. Congressional Record, October 31, 2000 at E2038.

(d) Subpoenaed documents from Fujisawa likewise indicate the companies' fraudulent efforts to manipulate reimbursements. One document between Fujisawa employees reveals the following:

Many thanks to Rick and Bruce for adjusting the AWP on the five gram Vanco. This should lead to more business . . . I would have liked to see us match Abbott's AWP for our complete Vanco, and Cefazolin line. I will settle for the five gram at \$1 below Abbott but that means that we will still have to compete at the other end of the equation. For example, if Abbott's AWP is \$163 we will have to be at least \$29 to have the same spread. Follow?

September 28, 2000 letter from House Committee on Ways and Means, Subcommittee on Health, to Alan F. Holmer, President, Pharmaceutical Research and Manufacturers of America,

reprinted in Congressional Record, September 28, 2000, Extension of Remarks, 146 Cong. Rec. E1622-01, *E1622 (2000).

168. A September 21, 2000 GAO Report determined that actual retail prices for top Medicaid/Medicare drugs, such as Albuterol and Ipratropium bromide, were 85 percent and 75 percent less than their AWP. Applying this range of percentages to Westchester's Medicaid costs, the overcharges add up to millions of dollars annually. GAO, *Payments for Covered Outpatient Drugs Exceed Providers' Cost*, September 2001 (GAO-01-1118) at 4.

169. That same GAO report found that:

Widely available discounts for 17 of the physician-billed drugs we examined averaged between 13 percent and 34 percent less than AWP.

For two other physician-billed drugs, Dolasetron mesylate and Leucovorin calcium, average discounts were considerably larger – 65 percent and 86 percent less than AWP.

GAO-01-1118 at 11-12.

170. The HHS OIG has issued a series of reports on pharmacy overcharges to the Medicaid program, based on data collected in 1994 and again in 1999. In its September 2002 report, the OIG summarized its findings. Pharmacies' actual acquisition cost for brand name prescription drugs was on average 21.8% below AWP. For generic drugs, actual acquisition costs were 65.9% below AWP. These numbers reflected considerably increased spreads as compared to the earlier data, which showed spreads of 18.3% and 42.5% for brand name and generic drugs respectively. HHS OIG, *Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Costs of Prescription Drugs* (A-06-02-00041) (September 16, 2002), at 1.

171. The OIG estimated that as much as \$1.08 billion nationwide could have been saved for the 200 most frequently reimbursed drugs in calendar year 1999 if

reimbursement had been based on a greater percentage discount off of AWP. HHS OIG, *Medicaid Pharmacy – Actual Cost of Brand Name Prescription Drug Products* (A-06-00-00023) (August 2001), at 3-4.

172. The OIG has recently warned that drug pricing practices in the private sector may have significant effects on Medicaid rebates:

Discounting arrangements are prevalent in the pharmaceutical industry and deserve careful scrutiny particularly because of their potential to implicate the Best Price requirements of the Medicaid Rebate Program. Because the Medicaid Rebate Program in many instances requires that states receive rebates based on the Best Price offered by a pharmaceutical manufacturer to other purchasers, manufacturers have a strong financial incentive to hide *de facto* pricing concessions to other purchasers to avoid passing on the same discounts to the states. Because of the potential direct and substantial effect of such practices on federal health care program expenditures and the interest of some manufacturers in avoiding price concessions that would trigger rebates to the states, any remuneration from a manufacturer to a purchaser, however characterized, should be carefully scrutinized.

OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23,731-35 (May 5, 2003).

173. A March 27, 2001 report entitled *Medicaid Drug Rebates – Sales to Repackagers Excluded From Best Price Determinations* (A-06-00-00056), issued by the HHS OIG studied the rebate issues for the manufacturers of the top 200 Medicaid reimbursed drugs for Fiscal Year (FY) 1999. It found that many manufacturers failed to include in their Best Price calculations submitted to the federal government discounted sales to repackagers, which buy drugs in bulk and then repackage them in smaller quantities for distribution:

7 out of 53 manufacturers excluded sales to 8 repackagers, 3 of which were HMO repackagers. Sales to HMOs are specifically required by statute to be included in a drug manufacturer's best price determination. As a result, Medicaid drug rebates totaling \$80.7 million for FY 1999 were lost because sales to HMOs were excluded from the best price determinations.

Id. at 1. The report found that “[i]n some instances the sales to the HMOs were at prices as much as 75 percent below the reported best price.” *Id.* at 4. Given the Model Rebate Agreement definition of Best Price, quoted above, these sales to repackagers should be accounted for in Best Price calculations. Yet they routinely are not.

174. The report went on to say that this review was a follow up to previous investigations conducted in response to congressional inquiries. Based on a more limited number of drugs and repackagers it was found that that two “repackagers were HMOs and that they were purchasing drugs significantly below the manufacturers’ reported best prices.” This limited study found a loss of \$27.8 million in Medicaid rebates for FY 1998. *Id.* at 1.

175. The report “recommended that the Health Care Financing Administration (HCFA) [now CMS] require drug manufacturers who excluded sales to HMOs from their Best Price to repay the lost rebates.” *Id.* at cover page. Rep. Henry A. Waxman (D-CA), who requested the report, said “This report shows that drug manufacturers have used drug repackaging to evade paying rebates to Medicaid.” *Drug Companies’ Repackaging Scheme Costs Taxpayers Over \$100 Million In 1998 And 1999*, April 5, 2001, pg. 1 of 1, available at http://www.house.gov/reform/min/pdfs/pdf_inves/pdf_medi_drug_IG_press.pdf.

176. Further evidence of non-compliance with Best Price reporting requirements is found in a March 25, 2003 report issued by the OIG. Five brand-name drug manufacturers were found to have overcharged AIDS Drug Assistance Programs, public hospitals, and other health care providers that participate in the U.S. Public Health Service’s 340B program, a program that provides low cost drugs to such providers based on the same Best Price formula as the Medicaid rebate provision. The inspector general found that the drug manufacturers failed to include in their calculations of Best Price the price of drugs sold to

HMO repackagers, resulting in millions of dollars of excess charges. Specific drug names and manufacturers were not mentioned in the report. *Pharmaceutical Manufacturers Overcharged 340B-Covered Entities*, March 2003 (A-06-01-00060), at 1.

177. The GAO, HHS OIG, and DOJ investigations of the fraudulent pricing practices undergirding this complaint are further described in the defendant-specific allegations below

VI. ALLEGATIONS PARTICULAR TO WESTCHESTER AND THE INDIVIDUAL DEFENDANTS

178. The following examples are merely illustrative of each defendant's unlawful activity, and are not intended to be an exact or exhaustive recitation of all of such activity engaged in by each defendant. Additional detail is peculiarly within defendant's control pending discovery.

A. ABBOTT

179. As set forth in detail in Exhibit A, the Westchester Medicaid program spent \$3.2 million for Abbott drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

180. Westchester alleges an intentionally false and misleading AWP for each Abbott drug listed on Exhibit A.

181. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Abbott drugs for which Westchester seeks relief.

182. As an example, in 2002 alone, the Westchester Medicaid program spent over \$1.7 million for Abbott's Depakote. Westchester's most popular dosage of Depakote was the 500 mg tablet EC. The estimated overcharge for this dosage as a result of

Abbott's false AWP is at least 20%. This translates into an overpayment of over \$362,000 by the Westchester Medicaid Program. *See* Exhibit B.

183. In connection with the wrongful conduct described herein, Abbott has been investigated by at least the United States Department of Justice, the United States Congress, Commonwealth of Massachusetts, the Office of Inspector General of the Department of Health and Human Services, the Attorneys General of California, Florida, Illinois, Ohio, Texas and Wisconsin, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse. The publicly available results of these investigations confirm Abbott's routine practice of reporting false and inflated wholesale pricing information and non-compliance with rebate obligations.

184. In a report published by HHS (the "HHS Report")¹¹, the DOJ documented at least 81 instances where the published AWP's for various dosages of 16 drugs manufactured by Abbott were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 16 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *RedBook*.

| Drug | Abbott's 2001 <i>RedBook</i> AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|-----------------------------|-------------------------------------|------------------------------|------------|-------------------|
| Acetylcysteine | \$ 35.87 | \$ 21.90 | \$ 13.97 | 64% |
| Acyclovir | \$ 1047.38 | \$ 349.05 | \$ 698.33 | 200% |
| Amikacin Sulfate | \$ 995.84 | \$ 125.00 | \$ 807.84 | 697% |
| Calcitriol (Calcijex) | \$ 1,390.66 | \$ 1079.00 | \$ 311.66 | 29% |
| Cimetidine Hydrochloride | \$ 214.34 | \$ 35.00 | \$ 179.34 | 512% |

¹¹ "An Additional Source of Average Wholesale Price Data In Pricing Drugs and Biologicals Covered by the Medicare Program," PM Rev. AB-00-86 (Sept. 8, 2000).

| Drug | Abbott's 2001 <i>RedBook</i> AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|-------------------------------------|---------------------------------------------|--------------------------------------|-------------------|--------------------------|
| Clindamycin Phosphate | \$ 340.52 | \$ 75.35 | \$ 265.17 | 352% |
| Dextrose | \$ 239.97 | \$ 3.91 | \$ 236.06 | 6,037% |
| Dextrose Sodium Chloride | \$ 304.38 | \$ 1.93 | \$ 302.45 | 15,671% |
| Diazepam | \$ 28.50 | \$ 2.03 | \$ 26.47 | 1,304% |
| Furosemide | \$ 74.52 | \$ 14.38 | \$ 60.14 | 418% |
| Gentamicin Sulfate | \$ 64.42 | \$.51 | \$ 63.91 | 12,531% |
| Heparin Lock Flush | \$ 38.30 | \$ 13.60 | \$ 24.70 | 182% |
| Metholprednisolone Sodium Succinate | \$ 34.08 | \$ 2.30 | \$ 31.78 | 1,382% |
| Sodium Chloride | \$ 670.89 | \$ 3.22 | \$ 667.67 | 20,735% |
| Tobramycin Sulfate | \$ 150.52 | \$ 2.94 | \$ 147.58 | 5,020% |
| Vancomycin Hydrochloride | \$ 382.14 | \$ 4.98 | \$ 377.16 | 7,574% |

185. In July 2003, Abbott agreed to pay \$622 million in criminal and civil penalties to resolve allegations that its Ross Products Unit defrauded Medicare and Medicaid by failing to report Best Price. In that proceeding, the U.S. Attorney's Office in the Southern District of Illinois probed whether Ross Products Unit failed to include in calculating Best Price that it had used kickbacks to boost sales and defraud government insurers by discounting or giving away products. Providers thereafter would seek government reimbursements at higher prices.

186. Abbott also was co-venturer with Japan's Takeda Chemical Industries, Ltd. in TAP Pharmaceuticals, which paid \$875 million in a 2001 settlement of allegations that TAP provided free and unreported samples of Lupron, a prostate cancer drug, to physicians with the understanding that they would bill Medicaid and Medicare for reimbursement based on the inflated AWP.

187. Abbott was among the drug companies to which Congressman Stark sent his October 31, 2000 letter, quoted above.

188. Abbott is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

189. Abbott also is the subject of the investigation led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is improperly using the nominal price exception to the Best Price reporting requirements.

B. ALCON

190. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$230,000 for Alcon drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

191. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

192. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Alcon drugs for which Westchester seeks relief.

193. As an example, in 2002 alone, the Westchester Medicaid program spent over \$26,000 for Alcon's Cipro HC. The estimated overcharge for this dosage as a result of Alcon's false AWP is at least 9%. This translates into an overpayment of over \$2,400 by the Westchester Medicaid Program. *See* Exhibit B.

194. In 2002 alone, the Westchester Medicaid program spent over \$128,000 for Alcon's Patanol. Westchester's most popular dosage of Patanol was the 0.1% eye drops. The estimated overcharge for this dosage as a result of Alcon's false AWP is at least

14%. This translates into an overpayment of over \$17,000 by the Westchester Medicaid Program. *See* Exhibit B.

C. ALLERGAN

195. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$277,000 for Allergan drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

196. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

197. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Allergan drugs for which Westchester seeks relief.

198. As an example, in 2002 alone, the Westchester Medicaid program spent over \$90,000 for Allergan's Lumigan. Westchester's most popular dosage of Lumigan was 0.03% eye drops. The estimated overcharge for this dosage as a result of Allergan's false AWP is at least 11%. This translates into an overpayment of over \$10,000 by the Westchester Medicaid Program. *See* Exhibit B.

D. THE ALPHARMA GROUP

199. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$334,000 for Alpharma Group (Alpharma and Purepac) drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

200. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

201. Certain multisource and generic Alharma Group drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on an intentionally false and inflated AWP. N.Y. Soc. Serv. L. § 367-a(9).

202. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Alharma Group drugs for which Westchester seeks relief.

203. As an example, in 2002 alone, the Westchester Medicaid program spent over \$91,000 for Purepac's Metformin. Westchester's most popular dosage was the 500 mg tablet, for which there was no FUL in 2002. *See* Exhibit C. The estimated overcharge for this dosage as a result of Purepac's false AWP is at least 41%. This translates into an overpayment of over \$37,000 by the Westchester Medicaid Program. *See* Exhibit B.

204. In 2002 alone, the Westchester Medicaid program spent over \$57,000 for Alharma's Ibuprofen. Westchester's most popular Ibuprofen was the 100mg/5mL suspension, for which there was no FUL in 2002. *See* Exhibit C. The estimated overcharge for this dosage as a result of Alharma's false AWP is at least 69%. This translates into an overpayment of over \$40,000 by the Westchester Medicaid Program. *See* Exhibit B.

205. Alharma is among the companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Medicaid Best Price and rebate requirements.

206. In connection with the wrongful conduct described herein, Purepac has been sued by the Massachusetts Attorney General.

E. THE AMGEN GROUP

207. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$1.4 million for Amgen Group (Amgen and Immunex) drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

208. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

209. Amgen admitted in a press release regarding Aranesp that AWP is “the common basis for reimbursement by payors” and “one of the factors used by Medicare to determine payment for drug charges”.

210. Exhibit B sets forth Westchester’s preliminary estimate of the extent of the overcharge on certain Amgen drugs for which Westchester seeks relief.

211. As an example, in 2002 alone, the Westchester Medicaid program spent over \$692,000 for Amgen’s Neupogen. Westchester’s most popular dosage of Neupogen was the 480mcg/0.8mL vial. The estimated overcharge for this dosage as a result of Amgen’s false AWP is at least 29%. This translates into an overpayment of over \$200,000 by the Westchester Medicaid Program. *See* Exhibit B.

212. Also in 2002 alone, the Westchester Medicaid program spent over \$193,000 for Amgen’s Enbrel 25MG kit. The estimated overcharge for this dosage as a result of Amgen’s false AWP is at least 26%. This translates into an overpayment of over \$49,000 by the Westchester Medicaid Program. *Id.*

213. As an example, the Westchester Medicaid program spent over \$436,000 for Amgen’s Epogen. Westchester’s most popular dosage of Epogen was the 40,000 U/ML vial. The estimated overcharge for this dosage as a result of Amgen’s false AWP is at

least 23%. This translates into an overpayment of over \$101,000 by the Westchester Medicaid Program. *Id.*

214. Amgen knows its purchasers' profits depend on reimbursement rates for drugs, and that Amgen's own sales and profits in turn depend on its customers' reimbursement payments and profits:

Our sales depend on payment and reimbursement from third-party payors, and a reduction in the payment rate or reimbursement rate could result in decreased sales of our products.

In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third-party payors . . . we believe that sales of Aranesp and Neulasta are and will be affected by government and private payor reimbursement policies. . . .If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will administer them, which could reduce the use of our products or cause us to reduce the price of our products. This could result in lower product sales or revenues . . . (Amgen 2002 Form 10-K at 43-44).

215. The Amgen Group admits that it reports AWP's for each of its drugs to the publishers. *See* Amgen's Answer to the Second Amended Complaint filed in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, Civil Action 01-CV-12257-PBS (MDL No. 1456 D. Mass.) at p.10, ¶ 160.

216. A 1993 OIG Report detailed how Amgen gave substantial year-end rebates to its customers based on their purchases of Epogen, one of the drugs at issue here. The report noted that Medicare and Medicaid beneficiaries did not receive the benefit of any rebates.

217. Thus, at all times relevant hereto, the Amgen Group has known that it can motivate pharmacies and PBMs to promote its drugs by providing substantial discounts while at the same time maintaining a false AWP.

218. In connection with the wrongful conduct described herein, the Amgen Group has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services and the Attorneys General of the States of Pennsylvania and Wisconsin.

219. Amgen also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is improperly using the nominal price exception to the Best Price reporting requirements.

F. ANDRX

220. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$273,000 for Andrx drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

221. Westchester alleges an allegedly intentionally false and misleading AWP for each drug listed on Exhibit A.

222. Certain multisource or generic Andrx drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWPs. N.Y. Soc. Serv. L. § 367-a(9).

223. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Andrx drugs for which Westchester seeks relief.

224. As an example, in 2002 alone, the Westchester Medicaid program spent over \$88,000 on Andrx's Metformin HCL, for which there was no FUL. *See* Exhibit C.

Westchester's most popular dosage was the 500 mg tablet. The estimated overcharge for this dosage as a result of Andrx's false AWP is at least 41%. This translates into an overpayment of over \$36,000 by the Westchester Medicaid Program. *See* Exhibit B.

225. In 2002 alone, the Westchester Medicaid program spent over \$118,000 for Andrx's Cartia XT, for which there was no FUL. *See* Exhibit C. Westchester's most popular dosage of Cartia XT was the 240mg capsule SA. . The estimated overcharge for this dosage as a result of Andrx's false AWP is at least 51%. This translates into an overpayment of over \$60,000 by the Westchester Medicaid Program. *See* Exhibit B.

G. ASTRAZENECA

226. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$6.1 million for AstraZeneca drugs in 2002. The specific drugs for which Westchester seeks relief includes those set forth in Exhibit A hereto.

227. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

228. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain AstraZeneca drugs for which Westchester seeks relief.

229. As an example, in 2002 alone, the Westchester Medicaid program spent over \$1.4 million for AstraZeneca's Prilosec. Westchester's most popular dosage of Prilosec was the 20 mg capsule DR. The estimated overcharge for this dosage as a result of AstraZeneca's false AWP is at least 28%. This translates into an overpayment of over \$399,000 by the Westchester Medicaid Program. *See* Exhibit B.

230. In connection with the wrongful conduct described herein AstraZeneca has been investigated by at least the United States Congress, the Department of

Justice, the Office of the Inspector General of the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration.

231. In January 2002, a federal grand jury in Wilmington, Delaware returned an indictment accusing a New Jersey doctor of conspiring with AstraZeneca to resell free samples of Zoladex®, a drug at issue here, that an AstraZeneca sales representatives had given the doctor. The indictment alleged that AstraZeneca (i) sold Zoladex® to the New Jersey doctor and others at prices substantially below the AWP reported by AstraZeneca, and (ii) provided the New Jersey doctor with materials showing how much more profit he could make by using Zoladex® instead of its competitor, Lupron®.

232. In June 2003, AstraZeneca pled guilty and paid \$291 million to settle the Zoladex® charges. The U.S. Food and Drug Administration said in its statement regarding the settlement, “AstraZeneca provided thousands of free samples of Zoladex® to physicians knowing that they would charge their patients and insurance programs for the samples.”

233. On May 29, 2003, AstraZeneca entered into a Corporate Integrity Agreement (“CIA”) with the OIG of the United States Department of Health and Human Services “to promote compliance” “with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. 1320a-7b(f))” (“Federal Health Care Program Requirements”). Contemporaneously, AstraZeneca entered into a Settlement Agreement with the United States and various states.

234. The CIA covers any individuals who sell or market government reimbursed products on behalf of AstraZeneca; calculate or report prices; and/or include, negotiate, implement or report information related to government contracts relating to federal

health care programs, including Medicare and the Medicaid drug rebate program (codified at 42 U.S.C. § 1396r-8 et seq.) The CIA also covers any AstraZeneca employee or agent responsible for “(1) sales and marketing activities for Government Reimbursed Products; (2) the calculation and reporting of prices for federal health care programs, including . . . Medicaid or (3) the negotiation, implementation, and any reporting of information related to government contracts.”

235. In addition to promising compliance with federal health care program requirements, the CIA requires AstraZeneca to establish a written code of conduct to be agreed to by each covered person that confirms AstraZeneca’s “commitment to full compliance with all federal health care program requirements, including its commitment to comply with all government contracting requirements and to market and sell its government reimbursed products in accordance with federal health care program requirements.”

236. The CIA requires further that AstraZeneca implement policies and procedures that address the code of conduct described above as well as :

(a) the calculation and reporting of accurate prices for government reimbursed products to certain entities, including CMS, the State Medicaid programs, and the drug price reporting services on which government agencies now rely (First DataBank Inc., the *RedBook*, etc.) or shall rely in the future;

(b) the proper calculation and reporting of all data and information reported to CMS and/or the State Medicaid programs in connection with the Medicaid drug rebate program, codified at 42. U.S.C. § 1396r-8;

(c) the proper uses and tracking of drug samples in accordance with all applicable requirements, including, but not limited to, the Prescription Drug Marketing Act, codified in 21 U.S.C. §§ 331, 333 and 352; and

(d) measures designed to promote marketing and sales practices that conform with all statutes, regulations and requirements applicable to government reimbursed products. The Policies and Procedures shall specify that AstraZeneca shall comply with the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b(1) & (2), and other applicable statutes, regulations or requirements.

237. The CIA contemplates monetary penalties for non-compliance, and the retention of an independent review organization, (“IRO”). The IRO shall perform two types of review: (1) a systems review of AstraZeneca’s systems, processes, policies and practices relating to the Medicaid drug rebate program (“Medicaid Rebate Systems Review”) and (2) a review of specific contract price transactions to determine whether those transactions were considered for purposes of determining Best Price in accordance with AstraZeneca’s policies and procedures and Medicaid drug rebate program requirements.

238. The publicly available results of these investigations and terms of the CIA confirm AstraZeneca’s routine practice of reporting false and inflated wholesale price information and non-compliance with rebate obligations.

239. AstraZeneca now is the subject of an investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

H. THE AVENTIS GROUP

240. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$1.5 million for Aventis Group (Aventis Pharm and Dermik) drugs in 2002. The specific drugs for which Westchester seeks relief are set forth in Exhibit A hereto.

241. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

242. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Aventis Group drugs for which Westchester seeks relief.

243. As an example, in 2002 alone, the Westchester Medicaid program spent over \$146,000 for the Aventis Group's DDAVP. Westchester's most popular dosage of DDAVP was the 0.2 mg tablet. The estimated overcharge for this dosage as a result of the Aventis Group's false AWP is at least 11%. This translates into an overpayment of over \$16,000 by the Westchester Medicaid Program. *See* Exhibit B.

244. In 2002 alone, the Westchester Medicaid program spent over \$192,000 for the Aventis Group's Allegra. Westchester's most popular dosage of Allegra was the 180mg tablet. The estimated overcharge for this dosage as a result of the Aventis Group's false AWP is at least 24%. This translates into an overpayment of over \$46,000 by the Westchester Medicaid Program. *See* Exhibit B.

245. In a report published by the DHHS (AB-00-86), the DOJ documented at least 15 instances where the published AWP for various dosages of 4 drugs manufactured by Aventis Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the 4 drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's

determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Aventis in the 2001 *RedBook*.

| Drug | 2001 <i>RedBook</i> AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|------------------------------------------|-------------------------|---------------------------|------------|-------------------|
| Anzemet Injectable (dolasetron Mesylate) | \$ 166.50 | \$ 74.08 | \$ 92.42 | 125% |
| Factor VIII/ Bioclate | \$ 1.25 | \$.91 | \$.34 | 37% |
| Factor VIII/ Helixate | \$ 1.18 | \$.78 | \$.40 | 51% |
| Gammar (immune globulin) | \$ 400.00 | \$ 296.67 | \$ 103.33 | 35% |

246. An OIG report (*See* "Medicare Reimbursement of Prescription Drugs," OEL-03-00-00310, Jan. 2001) further revealed that: (i) that AWP for all immune globulin 5 mg doses listed in the 1997 *RedBook* were inflated by an average spread of 32.21%; (ii) a 10 mg dose of Anzemet had a Medicare Median of \$14.82 and a Catalog Median of \$8.29, resulting in a spread of 78%; and (iii) a 20 mg dose of Taxotere had a Medicare Median of \$283.65 and a Catalog Median of \$8.29, resulting in a spread of 18.75%. (P006398-006424).

247. In connection with the wrongful conduct described herein Aventis Group has been investigated by at least the United States Department of Justice, the United States Congress, the Office of Inspector General of the Department of Health and Human Services, the Attorneys General for the states of California, Florida, Illinois, Montana, Pennsylvania, Texas and Wisconsin and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse. The publicly available results of these investigations confirm the Aventis Group's routine practice of reporting false and inflated wholesale pricing information and non-compliance with rebate obligations.

248. Aventis Pharm is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

249. Aventis Pharm also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

I. BARR

250. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$622,000 for Barr drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

251. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

252. Certain multisource or generic Barr drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWP. N.Y. Soc. Serv. L. § 367-a(9).

253. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Barr drugs for which Westchester seeks relief.

254. As an example, in 2002 alone, the Westchester Medicaid program spent over \$346,000 for Barr's Fluoxetine HCL, for which there was no FUL for the majority of 2002. *See* Exhibit C. Westchester's most popular dosage was the 20 mg capsule. The estimated overcharge for this dosage as a result of Barr's false AWP is at least 67%. This translates into an overpayment of over \$231,000 by the Westchester Medicaid Program. *See* Exhibit B.

255. In 2002 alone, the Westchester Medicaid program spent over \$141,000 for Barr's Tamoxifen, for which there was no FUL. *See* Exhibit C. Westchester's most popular dosage of Tamoxifen was the 20mg tablet. The estimated overcharge for this dosage as a result of Barr's false AWP is at least 83%. This translates into an overpayment of over \$117,000 by the Westchester Medicaid Program. *See* Exhibit B.

256. In connection with the wrongful conduct described herein, Barr has been sued by the Commonwealth of Massachusetts Office of the Attorney General. Prior to filing suit the Massachusetts AG had issued a subpoena to Barr for documents related to pricing and Medicaid reimbursement of select products in Massachusetts.

257. Barr also is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

J. BAXTER

258. As set forth in detail in Exhibit A, the Westchester Medicaid program spent \$164,000 for Baxter drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth set forth in Exhibit A hereto.

259. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

260. The United States Department of Justice, Department of Health and Human Services Office of Inspector General, the Attorney General for the State of California, the Attorney General for the State of Texas, the Attorney General for the State of Illinois, and the Committee on Commerce of the House of Representatives have all investigated Baxter.

261. In a September 28, 2000 letter to Alan F. Holmer, President, Pharmaceutical Research and Manufacturers of America Congressman Pete Stark made clear that Baxter both inflated AWP's to increase government reimbursement to its customers and gave free drugs to customers in order that they could obtain government reimbursement for these free drugs.

262. The purposeful inflation of AWP in order to manipulate reimbursement was made clear by Congressman Stark. Internal Baxter documents stated that "[i]ncreasing AWP's was a large part of our negotiations with the large homecare companies." *See* September 28, 2000 letter from House Committee on Ways and Means, Subcommittee on Health, to Alan F. Holmer, President, Pharmaceutical Research and Manufacturers of America, Washington, D.C. Congressional Record, Extension of Remarks at E1622.

263. Providing free samples of drugs knowing that those goods will be the basis of a fraudulent claim to the government is a clear violation of federal law. The use of the drug Recombinate in this manner was made clear by the following internal Baxter communication:

BAXTER: "The attached notice from Quantum Headquarters was sent on April 10th to all their centers regarding the reduction on Recombinate pricing. Please note that they want to continue to be invoiced at the \$.81 price. They have requested that we send them free product every quarter calculated by looking at the number of units purchased in that quarter and the \$.13 reduction in price . . . free product given to achieve overall price reduction."

September 28, 2000 letter from House Committee on Ways and Means, Subcommittee on Health, to Alan F. Holmer, President, Pharmaceutical Research and Manufacturers of America, Washington, D.C. Congressional Record, Extension of Remarks at E1622.

K. BAYER

264. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$396,000 for Bayer drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

265. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

266. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Bayer drugs for which Westchester seeks relief.

267. As an example, in 2002 alone, the Westchester Medicaid program spent over \$373,000 for Bayer's Cipro. Westchester's most popular dosage of Cipro was the 500 mg tablet. The estimated overcharge for this dosage as a result of Bayer's false AWP is at least 16%. This translates into an overpayment of over \$60,000 by the Westchester Medicaid Program. *See* Exhibit B.

268. Bayer's wrongful conduct concerning AWP manipulation and Best Price fraud is not speculative. In connection with the wrongful conduct described herein, Bayer has been investigated by at least the United States Department of Justice, the United States Congress, the Commonwealth of Massachusetts, and the Office of Inspector General of the Department of Health and Human Services.

269. In January 2002, Bayer agreed to pay a total of \$14 million to the United States and 45 states to settle allegations under the federal False Claims Act that the company caused physicians and other health care providers to submit fraudulently inflated reimbursement claims to state and federally funded Medicaid program. Bayer reached the agreement with the Justice Department, the United States Attorney's Office for the Southern

District of Florida in Miami, the Office of Inspector General for the Department of Health and Human Services, and a team of state negotiators from Maine, Nevada, New York and Washington representing the National Association of Medicaid Fraud Control Units.

270. The government's investigation of the allegations, contained in a *qui tam* or whistleblower lawsuit in which the government intervened against Bayer, revealed that, beginning in the early 1990's, Bayer falsely inflated the reported drug prices referred to by the industry as the Average Wholesale Price (AWP), the Direct Price, and the Wholesale Acquisition Cost used by State Governments to set the reimbursement rate for the Medicaid program. According to the DOJ's January 23, 2001 press release, by setting an extremely high AWP, and subsequently selling the product to doctors at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit from reimbursement paid to the by the government. The Bayer AWP's at issue in this settlement were Kogenate, Koate-HP, Gamimmune, which are widely used in treating hemophilia and immune deficiency diseases.

271. The Bayer investigation revealed that the practice in which Bayer selectively engaged, commonly referred to by drug manufacturers as "marketing the spread," also had the effect of discouraging market competition from manufacturers that do not inflate AWP's as a way of inducing doctors to purchase their products. In addition to entering into the monetary settlement, Bayer reached a five year agreement with the OIG of HHS that the company's conduct will be monitored by the government under a corporate integrity agreement. Under the compliance agreement, Bayer will provide the state and federal governments with the average selling prices of its drugs in order to facilitate the government's

setting of fair reimbursement rates for the company's products, and potentially, the products of any competitors attempting to take advantage of Bayer's cooperation.

272. This Bayer settlement also included settlement of allegations that Bayer knowingly underpaid the Medicaid program for rebates owed by it to the states.

273. In April 2003, Bayer settled certain charges in connection with its efforts to evade paying rebates to states' Medicaid programs which were based on the lowest drug prices they were paying to an HMO, Kaiser Permanente, for Cipro and another Bayer drug, Adalat CC. Bayer is to pay a total of \$275 million to resolve criminal charges and civil liabilities in connection with the fraudulent drug pricing of Cipro and Adalat. The criminal portion of the global agreement calls for Bayer to plead guilty to charges that it violated the Food, Drug and Cosmetic Act by failing to notify the FDA between August and December 1995, of its production of private label Cipro for Kaiser. Bayer has agreed to pay a criminal fine of \$5.6 million and will admit that it engaged in this conduct with the intent to defraud or mislead. In the civil portion of its global settlement, Bayer resolved its federal civil False Claims Act liabilities and pay the United States, 49 states, the District of Columbia, and Public Health Service Entities \$251 million in civil damages for losses suffered by the Medicaid program and the Public Health Service entities due to Bayer's failure to report its Kaiser private label price to the government as the true Best Price for its drugs.

274. The foregoing settlement implicates none of Westchester's AWP claims. To the extent it concerned Bayer's Best Price failures, at most, it may have some impact on two years' worth of rebate related damages.

L. BERLEX

275. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$200,000 for Berlex drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

276. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

277. Exhibit B sets forth Westchester's preliminary estimate of the extent of its overcharge on those Berlex drugs for which it paid the greatest amount.

278. As an example, in 2002 alone, the Westchester Medicaid program spent over \$200,000 on Berlex's Betaseron. Westchester's most popular dosage of Betaseron was the 0.3mg vial. The estimated overcharge for this dosage as a result of Berlex's false AWP is at least 12%. This translates into an overpayment of over \$23,000 by the Westchester Medicaid Program. *See* Exhibit B.

M. BIOGEN IDEC

279. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$347,000 for Biogen Idec drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

280. Westchester alleges an intentionally false and misleading AWP for the drug listed on Exhibit A.

281. Exhibit B sets forth Westchester's preliminary estimate of the extent of its overcharge on those Biogen drugs for which it paid the greatest amount.

282. As an example, in 2002 alone, the Westchester Medicaid program spent over \$347,000 on Biogen's Avonex. Westchester's most popular dosage of Avonex was

the Admin pack 30mcg v1. The estimated overcharge for this dosage as a result of Biogen's false AWP is at least 20%. This translates into an overpayment of over \$70,000 by the Westchester Medicaid Program. *See* Exhibit B.

N. BIOVAIL

283. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$113,000 for Biovail drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

284. Westchester alleges an intentionally false and misleading AWP for each Biovail drug listed on Exhibit A.

285. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Biovail drugs for which Westchester seeks relief.

286. As an example, in 2002 alone, the Westchester Medicaid program spent over \$67,000 for Biovail's Cardizem. Westchester's most popular dosage of Cardizem was the 360mg Capsule SA. The estimated overcharge for this dosage as a result of Biovail's false AWP is at least 22%. This translates into an overpayment of over \$15,000 by the Westchester Medicaid Program. *See* Exhibit B.

287. Biovail's practices with respect to Cardizem have been investigated by the U.S. Attorney, District of Massachusetts, and the Office of the Inspector General ("OIG") of Health and Human Services. Specifically, In August 2003, Biovail Corporation announced that it has received notification that the U.S. Office of the Inspector General (OIG) of Health and Human Services has initiated a preliminary administrative inquiry into the Company's clinical experience and marketing programs related to Cardizem L.A. Biovail is facing an investigation by the HHS Office of Inspector General (OIG) over whether payments

to physicians for participating in a survey about its new blood pressure drug were a financial inducement to prescribe the drug.¹²

O. BOEHRINGER GROUP

288. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$651,000 for Boehringer Group (Boehringer, Boehringer Pharm, Ben Venue, and Roxane) drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

289. Westchester alleges an intentionally false and misleading AWP for each Boehringer Group drug listed on Exhibit A

290. Certain multisource or generic Boehringer Group drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWPs. N.Y. Soc. Serv. L. § 367-a(9).

291. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Boehringer Group drugs for which Westchester seeks relief.

292. As an example, in 2002 alone, the Westchester Medicaid program spent over \$211,000 for Boehringer Pharm's Viramune. Westchester's most popular dosage of Viramune was the 200 mg tablet. The estimated overcharge for this dosage as a result of Boehringer Pharm's false AWP is at least 23%. This translates into an overpayment of over \$47,000 by the Westchester Medicaid Program. *See* Exhibit B.

¹² Biovail's misconduct is not confined to Cardizem and fraudulent AWPs. In June 2002, the Federal Trade Commission ("FTC") settled charges that Biovail illegally acquired an exclusive patent license and wrongfully listed that patent in the Orange Book for the purpose of blocking generic competition to its brand-name drug Tiazac. And, in August 2002, the FTC issued a consent order against Biovail and Elan Corporation PLC to resolve charges that they had entered into an agreement that unreasonably reduced competition in the market for the generic anti-hypertension drug, Adalat.

293. In 2002 alone, the Westchester Medicaid program spent over \$22,000 for Roxane's Azathioprine. Westchester's most popular dosage of Azathioprine was the 50 mg tablet. The estimated overcharge for this dosage as a result of Roxane's false AWP is at least 58%. This translates into an overpayment of over \$12,000 by the Westchester Medicaid Program. *Id.*

294. In connection with the wrongful conduct described herein, the Boehringer Group has been investigated by the Department of Justice, the Department of Health and Human Services Office of Inspector General, the Committee on Commerce of the House of Representatives, and the Attorneys General for the States of Nevada, Pennsylvania and Wisconsin. The publicly available results of these investigations confirm the Boehringer Group's routine practice of reporting false and inflated wholesale pricing information and non-compliance with rebate obligations.

295. For example, in a report published by HHS, the DOJ documented at least 32 instances where the published AWP for various dosages of nine drugs manufactured by the Boehringer Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the nine drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Boehringer Group in the 2001 *RedBook*.

| Drug | The Boehringer Group's 2001 <i>RedBook</i> AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|------------------|------------------------------------------------|---------------------------|------------|-------------------|
| Acyclovir Sodium | \$ 528.00 | \$ 207.00 | \$ 321.00 | 155% |
| Amikacin Sulfate | \$ 437.50 | \$ 65.53 | \$ 372.17 | 570% |
| Mitomycin | \$ 128.05 | \$ 51.83 | \$ 76.22 | 147% |

| | | | | |
|---------------------|-----------|-----------|-----------|--------|
| Cytarabine | \$ 62.50 | \$ 3.55 | \$ 58.95 | 1,661% |
| Doxorubicin HCL | \$ 945.98 | \$ 139.75 | \$ 806.23 | 577% |
| Etoposide | \$ 110.00 | \$ 8.45 | \$ 101.55 | 1,202% |
| Leucovorin Calcium | \$ 184.40 | \$ 2.76 | \$ 181.64 | 6,581% |
| Methotrexate Sodium | \$ 68.80 | \$ 2.63 | \$ 66.17 | 2,516% |
| Vinblastine Sulfate | \$ 212.50 | \$ 8.19 | \$ 204.31 | 2,495% |

296. Boehringer Group's Roxane is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

297. Boehringer also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

P. THE BMS GROUP

298. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$4 million for BMS Group (Bristol-Myers, Westwood and OTN and collectively referred to as "BMS") drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

299. Westchester alleges an intentionally false and misleading AWP for each BMS drug listed on Exhibit A

300. Certain generic or multisource BMS drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as described above, is based on intentionally false and inflated AWP's. N.Y. Soc. Serv. L. § 367-a(9).

301. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain BMS drugs for which Westchester seeks relief.

302. As an example, in 2002 alone, the Westchester Medicaid program spent over \$411,000 for the BMS' Glucophage. Westchester's most popular dosage of Glucophage was the 500 mg tablet. The estimated overcharge for this dosage as a result of BMS' false AWP is at least 10%. This translates into an overpayment of over \$42,000 by the Westchester Medicaid Program. *See Exhibit B.*

303. In 2002 alone, the Westchester Medicaid program spent over \$452,000 for BMS' Pravachol. Westchester's most popular dosage was the 20 mg tablet. The estimated overcharge for this dosage as a result of BMS' false AWP is at least 21%. This translates into an overpayment of over \$123,000 by the Westchester Medicaid Program. *Id.*

304. In connection with its the wrongful conduct described herein, BMS' has been investigated by the United California Department of Justice Office of the Attorney General, State of California Department of Justice, Bureau of Medi-Cal Fraud and Elder Abuse, and the U.S. House of Representatives Committee on Commerce, and the Attorneys General of the States of Florida, Pennsylvania, Texas and Wisconsin. The publicly available results of these investigations confirm BMS' routine practice of reporting false and inflated wholesale price information and non-compliance with rebate obligations.

305. For example, by letter dated February 27, 2001 to Bristol-Myers, Representative Stark outlined numerous examples of specific illegal practices by Bristol-Myers. Referring to a letter from Denis Kaszuba, a senior pricing analyst at Bristol-Myers to Medispan dated August 10, 1992, Rep. Stark noted:

Bristol has control over the AWP, DP, and WACs published for its drugs and directs national publishers to change their prices. Bristol directed a national publisher of drug prices to increase all of Bristol's AWP for oncology drugs by multiplying Bristol's supplied direct prices by a 25% factor rather than the previous 20.5% factor . . . Increasing the AWP created a spread that, in

itself, provided a financial kickback to oncologists for prescribing Bristol's cancer drugs.

306. In the same letter, Rep. Stark noted:

The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

147 Cong. Rec. E244-02, *E244 -E245 (2001).

307. BMS is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

308. BMS also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

Q. DEY

309. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$160,000 for Dey drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

310. Westchester alleges an intentionally false and misleading AWP for each Dey drug listed in Exhibit A.

311. Certain multisource or generic Dey drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWPs. N.Y. Soc. Serv. L. § 367-a(9).

312. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Dey drugs for which Westchester seeks relief.

313. In 2002 alone, the Westchester Medicaid program spent over \$71,000 for Dey's Albuterol. One of the more popular dosages was Albuterol 90 mcg inhaler, for which there was no FUL in 2002. *See* Exhibit C. The estimated overcharge for this dosage as a result of Dey's false AWP is at least 56%. This translates into an overpayment of over \$40,000 by the Westchester Medicaid Program. *See* Exhibit B.

314. In connection with the wrongful conduct described herein, Dey has been investigated by the United States Department of Justice, United States Department of Health and Human Services, Office of Inspector General, the United States District Attorney for the District of Massachusetts, and the Attorneys General for the States of California, Minnesota, Montana, Ohio, Pennsylvania, Texas, West Virginia and Wisconsin.

315. The Texas case concerned two of the Dey drugs at issue here, albuterol sulfate and ipratropium bromide. The Texas AG alleged that between 1995 and 1999 Dey defrauded the Texas State Medicaid program by reporting false wholesale pricing data for these drugs. In June 2003, Dey settled the Texas allegations for \$18,500,000.

316. The publicly available results of these investigations confirm Dey's routine practices of reporting false and inflated AWP's and of non-compliance with rebate obligations.

317. For example, in its own suit against Dey and other pharmaceutical manufacturers for AWP manipulation, the Attorney General for the State of Connecticut documented significant spreads between Dey's published AWP's and actual wholesale prices

for many of its drugs. Incorporated below are examples cited by the Connecticut Attorney General:

| Drug | NDC# | Year | AWP | ACTUAL PRICE | SPREAD | % OVERCHARGE |
|--------------------|---------------|-------------|------------|---------------------|---------------|---------------------|
| ALBUTEROL | 49502-0303-17 | 1996 | \$21.70 | \$3.25 | \$18.45 | 488% |
| IPATROPIUM BORMIDE | 49502-0685-03 | 2001 | \$44.10 | \$8.35 | \$35.58 | 355% |
| IPATROPIUM BORMIDE | 49502-0685-03 | 2000 | \$44.10 | \$11.45 | \$32.65 | 239% |
| IPATROPIUM BORMIDE | 49502-0685-03 | 1999 | \$44.10 | \$11.45 | \$30.11 | 177% |

318. In a report published by HHS, the DOJ documented at least 15 instances where the published AWP's for various dosages of 4 drugs manufactured by Dey were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each of the 4 drugs. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Dey in the 2001 RedBook.

| Drug in Lowest Dosage Form | 2001 RedBook AWP | DOJ Determined AWP | Difference | Percentage Spread |
|-----------------------------------|-------------------------|---------------------------|-------------------|--------------------------|
| Acetylcysteine | \$59.88 | \$25.80 | \$34.08 | 132% |
| Albuterol Sulfate | \$30.25 | \$9.17 | \$21.08 | 230% |
| Cromolyn Sodium | \$42.00 | \$23.01 | \$18.99 | 82% |
| Metaproterenol Sulfate | \$30.75 | \$11.29 | \$19.46 | 172% |

319. Dey is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements. Dey's Chief Financial Officer, Pamela Marrs, testified on December 7, 2004 that Dey did not lower its AWP's because to do so would cause it to lose customers. *Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much: Hearing Before the House Subcomm.*

on Oversight and Investigations, 108th Cong. Tr. 116-18 (2004) (statement of Pamela Marrs, Senior Vice President & CFO, Dey, Inc.)

R. EISAI

320. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$241,000 for Eisai drugs in 2002. The specific drugs for which Westchester seeks relief are set forth in Exhibit A hereto.

321. Westchester alleges an intentionally false and misleading AWP for each Eisai drug listed in Exhibit A.

322. Certain multisource or generic Eisai drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWP. N.Y. Soc. Serv. L. § 367-a(9).

323. Eisai also is the subject of an investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

324. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Eisai drugs for which Westchester seeks relief.

325. As an example, in 2002 alone, the Westchester Medicaid program spent over \$241,000 for Eisai's Aricept. Westchester's most popular dosage of Aricept was the 10 mg tablet, for which there was no FUL in 2002. *See* Exhibit C. The estimated overcharge for this dosage as a result of Eisai's false AWP is at least 24%. This translates into an overpayment of over \$57,000 by the Westchester Medicaid Program. *See* Exhibit B.

S. ELI LILLY

326. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$6.1 million for Eli Lilly drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

327. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

328. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Eli Lilly drugs for which Westchester seeks relief.

329. As an example, in 2002 alone, the Westchester Medicaid program spent over \$5.4 million for Eli Lilly's Zyprexa. Westchester's most popular dosage of Zyprexa was the 10 mg tablet. The estimated overcharge for this dosage as a result of Eli Lilly's false AWP is at least 23%. This translates into an overpayment of over \$1.2 million by the Westchester Medicaid Program. *See* Exhibit B.

330. Eli Lilly is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

331. Eli Lilly also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

332. Eli Lilly's unlawful efforts to create market share also include allegedly fraudulent marketing practices. The U.S. Attorney's Office in Pennsylvania is investigating Eli Lilly's marketing practices of certain drugs, including Evista, Prozac and Zyprexa, all at issue here.

T. ENDO

333. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$137,000 for Endo drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

334. Westchester alleges an intentionally false and misleading AWP for each Endo drug listed on Exhibit A.

335. Certain multisource or generic Endo drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWPs. N.Y. Soc. Serv. L. § 367-a(9).

336. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Endo drugs for which Westchester seeks relief.

337. As an example, in 2002 alone, the Westchester Medicaid program spent over \$28,000 for Endo's Lidoderm. Westchester's most popular dosage of Lidoderm was the 5% patch. The estimated overcharge for this dosage as a result of Endo's false AWP is at least 21%. This translates into an overpayment of over \$6,000 by the Westchester Medicaid Program. *See* Exhibit B.

U. ETHEX

338. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$48,000 for Ethex drugs in 2002. The specific for which Westchester seeks relief are set forth in Exhibit A hereto.

339. Exhibit A sets forth the allegedly intentionally false and misleading AWP that Ethex reported or caused to be reported for every dosage of every Ethex drug for which Westchester paid.

340. Certain multisource or generic Ethex drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWP. N.Y. Soc. Serv. L. § 367-a(9).

341. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Ethex drugs for which Westchester seeks relief.

342. As an example, in 2002 alone, the Westchester Medicaid program spent over \$9,000 for Ethex's Naproxen. Westchester's most popular dosage of Naproxen was the 500 mg tablet. The estimated overcharge for this dosage as a result of Ethex's false AWP is at least 80%. This translates into an overpayment of over \$7,000 by the Westchester Medicaid Program. *See* Exhibit B.

343. Ethex is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

344. In connection with the wrongful conduct described herein, Ethex has been sued by the Massachusetts Attorney General.

V. THE FOREST GROUP

345. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$581,000 for Forest Group (Forest and Forest Pharm) drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

346. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

347. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Forest Group drugs for which Westchester seeks relief.

348. As an example, in 2002 alone, the Westchester Medicaid program spent over \$581,000 for Forest Pharm's Celexa. Westchester's most popular dosage of Celexa was the 20 mg tablet. The estimated overcharge for this dosage as a result of Forest Pharm's false AWP is at least 19%. This translates into an overpayment of over \$111,000 by the Westchester Medicaid Program. *See Exhibit B.*

349. Forest Pharm now is the subject of an investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

350. Forest Pharm now is the subject of an investigation referred to above by the Office of the Inspector General of the Office of Personnel Management concerning marketing practices for mental health drugs.

W. THE FUJISAWA GROUP

351. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$391,000 for Fujisawa Group (Fujisawa and Fujisawa USA) drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

352. Westchester alleges an intentionally false and misleading AWP for each Fujisawa Group drug listed on Exhibit A.

353. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Fujisawa Group drugs for which Westchester seeks relief.

354. As an example, in 2002 alone, the Westchester Medicaid program spent over \$334,000 for the Fujisawa Group's Prograf. Westchester's most popular dosage of Prograf was the 1 mg capsule. The estimated overcharge for this dosage as a result of the

Fujisawa Group's false AWP is at least 19%. This translates into an overpayment of over \$62,000 by the Westchester Medicaid Program. *See* Exhibit B.

355. In connection with the wrongful conduct described herein, the Fujisawa Group has been investigated by at least the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorneys General for the State of Montana, Texas and California. The publicly available results of these investigations confirm the Fujisawa Group's routine practice of reporting false and inflated wholesale price information and non-compliance with rebate obligations.

X. GENENTECH

356. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$20,000 for Genentech drugs in 2002. The specific drugs paid for by Westchester and for which Westchester seeks relief include those set forth in Exhibit A hereto.

357. Westchester alleges an intentionally false and misleading AWP for each Genentech drug listed on Exhibit A.

358. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Genentech drugs for which Westchester seeks relief.

359. As an example, in 2002 alone, the Westchester Medicaid program spent over \$20,000 for Genentech's Pulmozyme. Westchester's most popular dosage of Pulmozyme was the 1MG/ML AMPUL. The estimated overcharge for this dosage as a result of Genentech's false AWP is at least 22%. This translates into an overpayment of over \$4,000 by the Westchester Medicaid Program. *See* Exhibit B.

Y. GENZYME

360. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$210,000 for Genzyme drugs in 2002. The specific drugs paid for by and on behalf Westchester and for which Westchester seeks relief include those set forth in Exhibit A hereto.

361. Westchester alleges an intentionally false and misleading AWP for each Genzyme drug listed on Exhibit A.

362. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Genzyme drugs for which Westchester seeks relief.

363. As an example, in 2002 alone, the Westchester Medicaid program spent over \$210,000 for Genzyme's Renagel. Westchester's most popular dosage of Renagel was the 800 mg tablet. The estimated overcharge for this dosage as a result of Genzyme's false AWP is at least 17%. This translates into an overpayment of over \$34,000 by the Westchester Medicaid Program. *See* Exhibit B.

Z. GILEAD

364. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$426,000 for Gilead drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

365. Westchester alleges an intentionally false and misleading AWP for each Gilead drug listed on Exhibit A.

366. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Gilead drugs for which Westchester seeks relief.

367. As an example, in 2002 alone, the Westchester Medicaid program spent over \$426,000 for Gilead's Viread. Westchester's most popular dosage of Viread was the 300 mg tablet. The estimated overcharge for this dosage as a result of Genzyme's false AWP is at least 22%. This translates into an overpayment of over \$93,000 by the Westchester Medicaid Program. *See Exhibit B.*

AA. THE GSK GROUP

368. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$8.8 million for GSK Group (GSK, SmithKline, Cerenex) drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

369. Westchester alleges an intentionally false and misleading AWP for each GSK Group drug listed on Exhibit A.

370. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain GSK Group drugs for which Westchester seeks relief.

371. As an example, in 2002 alone, the Westchester Medicaid program spent over \$1.1 million for GSK's Combivir tablet. The estimated overcharge for this dosage as a result of GSK's false AWP is at least 25%. This translates into an overpayment of over \$282,000 by the Westchester Medicaid Program. *See Exhibit B.*

372. In connection with the wrongful conduct described herein, GSK Group has been investigated by the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorneys General for the States of California, Colorado, Nevada, New York, Pennsylvania, Texas and Wisconsin.

373. The publicly available results of these investigations confirm GSK Group's routine practice of reporting false and inflated wholesale price information and non-compliance with rebate obligations. For example, GSK Group recently agreed to pay in excess of \$87 million to settle federal False Claims Act allegations that GSK Group repackaged and privately labeled Paxil, an antidepressant and Flonase, a nasal spray for Kaiser at discounted prices, but failed to report these lower prices as Best Prices to the government.

374. On April 13, 2003, SmithKline Beecham Corporation, d/b/a/ GlaxoSmithKline entered into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services "to promote compliance" "with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))" ("Federal Health Care Program Requirements"). Contemporaneously GSK entered into a Settlement Agreement with the United States and various states.

375. Persons covered by the "CIA" include all employees of the U.S. pharmaceuticals division of GSK responsible for the, *inter alia*, "reporting of pricing information for any products that are reimbursed by federal health care programs, including under the Medicaid drug rebate program, codified at 42 U.S.C. § 1396r-8" and "obligations related to government contracts, including the agreements entered with the Department of Health and Human Services under the Medicaid drug rebate program and the drug pricing program under the Public Health Service (PHS) Act, 42 U.S.C. § 256."

376. In addition to promising compliance with federal health care program requirements, the CIA requires GSK to establish a written code of conduct to be agreed to by each covered person that confirms GSK's "commitment to full compliance with

all federal health care program requirements, including its commitment to comply with all government contracting requirements and to market and sell its Government Reimbursed Products in accordance with federal health care program requirements.”

377. The CIA requires further that GSK implement policies and procedures that address:

(a) The code of conduct described above as well as;

(b) The methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services (“CMS”) and/or the state Medicaid programs in connection with the Medicaid drug rebate program;

(c) Promotional practices that conform with all applicable federal health care program requirements, including the Medicaid drug rebate program and the Federal anti-kickback statute, codified at 42. U.S.C. § 1302a-7b; and

(d) The requirements of all government contracts, including those under the Medicaid drug pricing program.

378. The CIA contemplates monetary penalties for non-compliance, and the retention of an independent review organization, (“IRO”). The IRO performs two types of review: (1) a systems review of GSK’s systems, processes, policies and practices relating to the Medicaid drug rebate program (“Medicaid Rebate Systems Review”) and (2) a review of specific contract price transactions to determine whether those transactions were considered for purposes of determining Best Price in accordance with GSK’s policies and procedures and Medicaid drug rebate program requirements.

379. CIA notwithstanding, GSK’s wrongful price reporting continues. GSK is among the pharmaceutical companies now under investigation by the House

Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

380. GSK Group also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

BB. THE HOFFMAN-LAROCHE GROUP

381. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$649,000 for Hoffman-LaRoche Group (Hoffman-LaRoche and Roche) drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

382. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

383. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Hoffman-LaRoche Group drugs for which Westchester seeks relief.

384. As an example, in 2002 alone, the Westchester Medicaid program spent over \$45,000 for Hoffman-LaRoche Group's Invirase. Westchester's most popular dosage of Invirase was the 200 mg capsule. The estimated overcharge for this dosage as a result of Hoffman-LaRoche Group's false AWP is at least 23%. This translates into an overpayment of over \$10,000 by the Westchester Medicaid Program. *See* Exhibit B.

385. Hoffman-LaRoche is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

386. Hoffman-LaRoche also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

CC. THE IVAX GROUP

387. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$801,000 for Ivax Group (Ivax and Ivax Pharm) drugs in 2002. The specific drugs paid for which Westchester seeks relief include those set forth in Exhibit A hereto.

388. Westchester alleges an intentionally false and misleading AWP for each Ivax Group drug listed on Exhibit A.

389. Certain multisource or generic Ivax Group drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWP's. N.Y. Soc. Serv. L. § 367-a(9).

390. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Ivax Group drugs for which Westchester seeks relief.

391. As an example, in 2002 alone, the Westchester Medicaid program spent over \$207,000 for the Ivax Group's Albuterol. Westchester's most popular dosage of Albuterol was the 90 mcg inhaler, for which there was no FUL in 2002. The estimated overcharge for this dosage as a result of Ivax Group's false AWP's is at least 68%. This translates into an overpayment of over \$140,000 by the Westchester Medicaid Program. *See* Exhibit B.

392. The Ivax Group defendants are among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and

Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

393. In connection with the wrongful conduct described herein, Ivax is being sued by the Attorney General for the Commonwealth of Massachusetts.

DD. JOHNSON & JOHNSON GROUP

394. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$9 million for J&J Group (J&J, Janssen, Ortho Biotech, Ortho-McNeil, McNeil) drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

395. Westchester alleges an intentionally false and misleading AWP for each J&J Group drug listed on Exhibit A.

396. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain J&J drugs for which Westchester seeks relief.

397. As an example, in 2002 alone, the Westchester Medicaid program spent over \$2 million for Ortho Biotech's Procrit. Westchester's most popular dosage of Procrit was the 40,000 u/mL vial. The estimated overcharge for this dosage as a result of Ortho Biotech's false AWPs is at least 27%. This translates into an overpayment of over \$546,000 by the Westchester Medicaid Program. *See* Exhibit B.

398. In 2002 alone, the Westchester Medicaid program spent over \$292,000 for Ortho-McNeil's Levaquin. Westchester's most popular dosage was the 500 mg tablet. The estimated overcharge for this dosage as a result of Ortho-McNeil's false AWPs is at least 18%. This translates into an overpayment of over \$51,000 by the Westchester Medicaid Program. *Id.*

399. In 2002 alone, the Westchester Medicaid program spent over \$4.6 million for Janssen's Risperdal. Westchester's most popular dosage was the 3 mg tablet. The estimated overcharge for this dosage as a result of Janssen's false AWP is at least 11%. This translates into an overpayment of over \$519,000 by the Westchester Medicaid Program. *Id.*

400. In connection with the wrongful conduct described herein, the J&J defendants have been investigated by the General Accounting Office and the Office of the Attorney General for the Commonwealth of Massachusetts. The publicly available results of these investigations confirm J&J's routine practice of reporting false and inflated wholesale pricing information and non-compliance with rebate obligations. J& J is also being sued by the Pennsylvania AG in connection with the same wrongdoing at issue here.

401. For example, a September 2001 GAO report documented fraudulently inflated AWP for epoetin alpha, sold by J&J as Procrit. J&J and Amgen are identified in the *RedBook* as the only two sources for epoetin alpha.

402. J&J is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

403. J&J is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

404. Janssen now is the subject of an investigation by the Office of the Inspector General of the Office of Personnel Management concerning marketing practices for mental health drugs.

405. Ortho McNeil was subpoenaed on April 9, 2004 by the U.S. Attorney in Boston for information regarding its prescription drug marketing and sales practices.

EE. THE KING GROUP

406. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$233,000 for King Group (King and Monarch) drugs in 2002. The specific drugs for which Westchester seeks relief are set forth in Exhibit A hereto.

407. Westchester alleges an intentionally false and misleading AWP for each King Group drug listed on Exhibit A.

408. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain King drugs for which Westchester seeks relief.

409. As an example, in 2002 alone, the Westchester Medicaid program spent over \$233,000 for the King Group's Altace. Westchester's most popular dosage of Altace was the 10 mg capsule. The estimated overcharge for this dosage as a result of the King Group's false AWPs is at least 7%. This translates into an overpayment of over \$16,000 by the Westchester Medicaid Program. *See* Exhibit B.

410. In connection with the wrongful conduct described herein, the King Group is being investigated by OIG-HHS, Department of Veterans Affairs, Department of Justice, Centers for Medicaid and Medicaid Services, the Public Health Service and the Securities and Exchange Commission.

411. King disclosed in its 2003 Annual Report that it owed Medicaid and other government health programs about \$46.5 million in unpaid rebates. King estimated that

it underpaid Medicaid by \$0.9 million from 1994-1997. An internal audit found that an additional \$18.9 million was due.

FF. MEDIMMUNE

412. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$1 million for MedImmune drugs in 2002. The specific drugs for which Westchester seeks relief are set forth in Exhibit A hereto.

413. Westchester alleges an intentionally false and misleading AWP for Synagis as listed on Exhibit A.

414. MedImmune has conceded that it inflates its reported AWP for Synagis to compensate for administrative costs. Specifically, in the Suffolk County AWP matter MedImmune states “a physician administering Synagis encounters costs of administration which Synagis AWP is used to cover.”

415. Exhibit B sets forth Westchester’s preliminary estimate of the extent of the overcharge for Synagis.

416. In 2002 alone, the Westchester Medicaid program spent over \$1 million for MedImmune’s Synagis. Westchester’s most popular dosage of Synagis was the 100 mg vial. The estimated overcharge for this dosage as a result of MedImmune’s false AWP is at least 27%. This translates into an overpayment of over \$293,000 by the Westchester Medicaid Program. *See* Exhibit B.

417. While competition is not necessary in order for defendants to have motivation to inflate AWP (as evidenced by MedImmune’s concession that they inflate AWP to compensate for administrative costs), MedImmune’s Synagis faces competition from Immune Globulin and alternative preventive therapies.

418. Since at least 1998, MedImmune has had a joint marketing agreement with Abbott's Ross Products Unit to promote Synagis. Expenditures on behalf of Westchester Medicaid recipients have increased substantially in the years since this joint marketing agreement was signed.

GG. MERCK

419. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$3.8 million for Merck drugs in 2002. The specific drugs for which Westchester seeks relief are set forth in Exhibit A hereto.

420. Westchester alleges an intentionally false and misleading AWP for each Merck drug listed on Exhibit A.

421. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Merck drugs for which Westchester seeks relief.

422. As an example, in 2002 alone, the Westchester Medicaid program spent over \$1 million for Merck's Zocor. Westchester's most popular dosage of Zocor was the 20 mg tablet. The estimated overcharge for this dosage as a result of Merck's false AWPs is at least 24%. This translates into an overpayment of over \$249,000 by the Westchester Medicaid Program. *See* Exhibit B.

423. In connection with the wrongful conduct described herein, Merck has been investigated by the U.S. Department of Justice and the Attorney General of Texas.

424. Merck also is the subject of the investigation led referred to above by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

HH. THE MYLAN GROUP

425. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$803,000 for Mylan Group (Mylan Labs, Mylan Pharm, UDL Labs) drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

426. Westchester alleges an intentionally false and misleading AWP for each Mylan Group drug listed on Exhibit A.

427. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Mylan Group drugs for which Westchester seeks relief.

428. Certain multisource or generic Mylan Group drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWPs. N.Y. Soc. Serv. L. § 367-a(9).

429. As an example, in 2002 alone, the Westchester Medicaid program spent over \$114,000 for the Mylan Group's Metformin HCL. Westchester's most popular dosage of Metformin HCL was the 500 mg tablet, for which there was no FUL. *See* Exhibit C. The estimated overcharge for this dosage as a result of Mylan Group's false AWPs is at least 41%. This translates into an overpayment of over \$46,000 by the Westchester Medicaid Program. *See* Exhibit B.

430. Mylan and its subsidiary UDL are among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

431. In connection with the wrongful conduct described herein, Mylan has been investigated by at least the Commonwealth of Massachusetts.

II. THE NOVARTIS GROUP

432. As set forth in detail in Exhibit A, the Westchester Medicaid Program spent over \$3.6 million for Novartis Group (Novartis and Sandoz (formerly Geneva)) drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

433. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

434. Certain multisource or generic Novartis Group drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWPs. N.Y. Soc. Serv. L. § 367-a (9).

435. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Novartis Group drugs for which Westchester seeks relief.

436. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$75,000 for the Novartis Group's Fluoxetine HCL. One of Westchester's most popular dosages of the Novartis Group's Fluoxetine HCL was the 20 mg capsule, for which there was no FUL for the majority of 2002. *See* Exhibit C. The estimated overcharge for this dosage as a result of the Novartis Group's false AWPs is at least 95%. This translates into an overpayment of over \$71,000 by the Westchester Medicaid Program. *See* Exhibit B.

437. In 2002 alone, the Westchester Medicaid Program spent over \$36,000 for the Novartis Group's Atenolol. Westchester's most popular dosage of Atenolol

was the 50 mg tablet. The estimated overcharge for this dosage as a result of the Novartis Group's false AWP is at least 84%. This translates into an overpayment of over \$30,000 by the Westchester Medicaid Program. *See* Exhibit B.

438. In connection with the wrongful conduct described herein, Novartis has been investigated by at least the Office of Inspector General of the Department of Health and Human Services.

439. Geneva (now Sandoz) is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

JJ. NORDISK

440. As set forth in detail in Exhibit A, the Westchester Medicaid Program spent over \$31,000 for Nordisk drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

441. Westchester alleges an intentionally false and misleading AWP for each drug listed on Exhibit A.

442. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Nordisk drugs for which Westchester seeks relief.

443. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$31,000 for Nordisk's Prandin. Westchester's most popular dosage of Prandin was the 2MG tablet. The estimated overcharge for this dosage as a result of Nordisk's false AWP is at least 3%. This translates into an overpayment of over \$900 by the Westchester Medicaid Program. *See* Exhibit B.

KK. ORGANON

444. As set forth in detail in Exhibit A, the Westchester Medicaid Program spent over \$165,000 for Organon drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

445. Exhibit A sets forth the allegedly intentionally false and misleading AWP that Organon reported or caused to be reported for every dosage of every Organon drug for which Westchester paid.

446. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Organon drugs for which Westchester seeks relief.

447. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$165,000 for Organon's Remeron. Westchester's most popular dosage of Remeron was the 15 mg tablet. The estimated overcharge for this dosage as a result of Organon's false AWPs is at least 19%. This translates into an overpayment of over \$31,000 by the Westchester Medicaid Program. *See* Exhibit B.

LL. PAR

448. As set forth in detail in Exhibit A, the Westchester Medicaid program spent over \$409,000 for Par drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

449. Westchester alleges an intentionally false and misleading AWP for each Par drug listed on Exhibit A.

450. Certain multisource or generic Par drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWPs. N.Y. Soc. Serv. L. § 367-a(9).

451. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Par drugs for which Westchester seeks relief.

452. As an example, in 2002 alone, the Westchester Medicaid program spent over \$195,000 for Par's Fluoxetine HCL. One of Westchester's dosages of Fluoxetine HCL was the 20 mg tablet, for which there was no FUL for the majority of 2002. *See* Exhibit C. The estimated overcharge for this dosage as a result of Par's false AWP is at least 95%. This translates into an overpayment of over \$185,000 by the Westchester Medicaid Program. *See* Exhibit B.

453. In connection with the wrongful conduct described herein, Par has been investigated by at least the Commonwealth of Massachusetts.

454. Par is also among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

MM. THE PFIZER GROUP

455. As set forth in detail in Exhibit A, the Westchester Medicaid program spent \$10.5 million for Pfizer Group drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

456. Westchester alleges an intentionally false and misleading AWP for each Pfizer Group drug listed on Exhibit A.

457. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Pfizer Group drugs for which Westchester seeks relief.

458. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$1.5 million for Pfizer Group's Lipitor. Westchester's most popular dosage of

Lipitor was the 10mg tablet. The estimated overcharge for this dosage as a result of Pfizer Group's false AWP's is at least 26%. This translates into an overpayment of over \$413,000 by the Westchester Medicaid Program. *See* Exhibit B.

459. In connection with the wrongful conduct described herein, members of the Pfizer Group have been investigated as follows:

460. Pfizer has been investigated by the Office of the Inspector General of the Department of Health and Human Services and has entered into a \$49 million settlement arising from illegal practices with respect to Lipitor. The OIG found that Pfizer had been providing unrestricted educational grants and rebates that were in fact discounts off the purchase price of Lipitor. Pfizer concealed these discounts from states who were entitled to receive the "Best Price" for Lipitor.

461. On October 24, 2002, Pfizer entered into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services "to promote compliance" "with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. 1320a-7b(f))" ("Federal Health Care Program Requirements"). Contemporaneously Pfizer entered into a Settlement Agreement with the United States and various states.

a) The CIA applies specifically, to, *inter alia*, "all employees of the Pfizer Pharmaceuticals Group whose job responsibilities directly relate to the gathering, calculation, verification or reporting of information for purposes of the Medicaid Drug Rebate program" (codified at 42. U.S.C. 1396r-8 et seq.)

b) In addition to promising compliance with federal health care program requirements, the CIA requires Pfizer to establish a written code of conduct to be agreed to by each covered person that confirms Pfizer's "commitment to full compliance with all federal health care program requirements, including its commitment to comply with all government contracting requirements and to market and sell its Government Reimbursed Products in accordance with federal health care program requirements."

c) The CIA requires further that Pfizer implement policies and procedures that address: The code of conduct described above as well as; The methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services ("CMS") and/or the state Medicaid programs in connection with the Medicaid Drug Rebate Program; and Promotional practices that conform with all applicable federal health care program requirements, including the Medicaid Drug Rebate Program and the Federal Anti-Kickback Statute, codified at 42. U.S.C. 1302a-7b.

d) The CIA contemplates monetary penalties for non-compliance, and the retention of an independent review organization, ("IRO"). The IRO shall perform two types of review: (1) a systems review of Pfizer's systems, processes, policies and practices relating to the Medicaid Drug Rebate program ("Medicaid Rebate Systems Review") and (2) a review of specific contract price transactions to determine whether those transactions were considered for purposes of determining Best Price in accordance with Pfizer's policies and procedures and Medicaid Drug Rebate program requirements.

462. Pfizer and Pharmacia are among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

463. In addition, Pfizer has been investigated by the General Accounting Office. Pfizer is singularly secretive when it comes to pricing data as it was the only drug company to initially refuse to voluntarily cooperate with this GAO rebate audit; a subpoena had to issue ultimately (subpoenas from the GAO are unusual). Ten other drug makers complied with the GAO query.

464. Pfizer also is the subject of the investigation led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is improperly using the Nominal Price Exception to the Best Price reporting requirements.

465. Pharmacia and its subsidiaries have been investigated by the Department of Justice, the Texas Attorney General, the California Attorney General, the Massachusetts Attorney General, the Attorney General of the State of Connecticut, the Attorney General of the State of New York, the Department of Health and Human Services Office of Inspector General and the US Congress.

466. Pharmacia was among the drug companies to which Congressman Stark sent his October 31, 2000 letter, quoted above.

467. Congressman Stark took issue with the Pharmacia Group's AWP manipulation in an October 2000 letter in which he says "The manipulated disparities between your company's reported AWP's and DP's [Direct Prices] are staggering. For example, in 1997,

Pharmacia & Upjohn reported an AWP for its Chemotherapy drug Vincasar of \$741.50 when in truth its list price was \$593.20.”

468. A May 2000 Justice Department memo to the states confirmed Pharmacia’s practice of AWP manipulation. According to the Justice Department, Pharmacia drug Andriamycin had an April 2000 AWP of \$241.36 while DOJ reported the true wholesale price to be \$33.43. Similarly, Pharmacia drug Toposar had an April 2000 AWP of \$28.38, while retailers were able to purchase the drug for \$1.70. See www.cancerpage.com/cancernews/cancernews2590.htm.

469. Pfizer likewise is now under investigation by numerous Attorneys General for promoting off-label uses for its drug Zoloft, a drug at issue here. Medicaid funds are not to be used for off-label promotion and to the extent Pfizer has engaged in this wrongful activity, Westchester has been additionally harmed.

NN. PURDUE

470. As set forth in detail in Exhibit A, the Westchester Medicaid program spent \$457,000 for Purdue drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

471. Westchester alleges an intentionally false and misleading AWP for each Purdue drug listed on Exhibit A.

472. Purdue is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

OO. RELIANT

473. As set forth in detail in Exhibit A, the Westchester Medicaid Program spent over \$170,000 for Reliant drugs in 2002. The specific drugs for which Westchester seeks relief are set forth in Exhibit A hereto.

474. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Reliant drugs for which Westchester seeks relief.

475. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$170,000 for Reliant's Axid. Westchester's most popular dosage of Axid was the 150 mg capsule, for which there was no FUL in 2002. *See* Exhibit C. The estimated overcharge for this dosage as a result of Axid's false AWP is at least 28%. This translates into an overpayment of over \$47,000 by the Westchester Medicaid Program. *See* Exhibit B.

PP. SANOFI

476. As set forth in detail in Exhibit A, the Westchester Medicaid Program spent over \$1 million for Sanofi drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

477. Westchester alleges an intentionally false and misleading AWP for each Sanofi drug listed on Exhibit A.

478. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Sanofi drugs for which Westchester seeks relief.

479. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$1 million for Sanofi's Ambien. Westchester's most popular dosage of Ambien was the 10 mg tablet. The estimated overcharge for this dosage as a result of Sanofi's false AWPs

is at least 24%. This translates into an overpayment of over \$252,000 by the Westchester Medicaid Program. *See* Exhibit B.

480. Sanofi is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

QQ. THE SCHERING GROUP

481. As set forth in detail in Exhibit A, the Westchester Medicaid Program spent over \$2.3 million for Schering Group (Schering, Schering Plough, and Warrick) drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

482. Westchester alleges an intentionally false and misleading AWP for each Schering Group drug listed on Exhibit A.

483. Certain multisource or generic Schering Group drugs, particularly drugs manufactured by Warrick, listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWPs. N.Y. Soc. Serv. L. § 367-a(9).

484. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Schering Group drugs for which Westchester seeks relief.

485. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$581,000 for Schering's Claritin. Westchester's most popular dosage of Claritin was the 10 mg tablet. The estimated overcharge for this dosage as a result of Schering's false AWPs is at least 15%. This translates into an overpayment of over \$87,000 by the Westchester Medicaid Program. *See* Exhibit B.

486. In 2002 alone, the Westchester Medicaid Program spent over \$352,000 for Warrick's Albuterol. The most popular unit of Albuterol was the 90mcg Aerosol, for which there was no FUL in 2002. *See* Exhibit C. The estimated overcharge for this dosage as a result of Warrick's false AWP is at least 55%. This translates into an overpayment of over \$193,000 by the Westchester Medicaid Program. *See* Exhibit B.

487. On July 16, 2004, it was announced that Schering has agreed to pay \$350 million in fines and plead guilty to criminal charges that it cheated Medicaid. The settlement stems from a six-year probe prompted by three whistleblowers who accused Schering of selling its products to private health-care providers for far less than it sold them to Medicaid. As part of the settlement, Schering is expected to admit it gave grants to private providers to conduct patient education and marketing programs as part of a scheme to induce them to buy the company's drugs at relatively high prices. Schering-Plough then billed Medicaid at these high prices without accounting for the offsetting grants.

488. In April 2004, Schering announced that it was paying \$27 million to settle charges brought in 2000 by the Texas Attorney General which revealed that Schering-Plough, with its subsidiary Warrick, had defrauded the State of Texas. Investigators determined that Schering-Plough provided the greatest "spread" amongst the drug companies selling Albuterol (one of the drugs paid for by Westchester) in Texas, and thereby obtained the largest market share for Albuterol. Schering-Plough sold a box of Albuterol to pharmacies for \$13.50, while it charged the Texas Medicaid program \$40.30, a 200% increase. *See* Cornyn Sues Three Drug Companies for Medicaid Fraud, Press Release by the Office of the Attorney General, State of Texas, September 7, 2000 (www.oag.state.tx.us.gov).

489. This follows a 2003 announcement by Schering that it was the subject of a federal grand jury investigation and criminal investigation led by the U.S. Attorney for the District of Massachusetts. The investigation concerned (i) providing remuneration, such as drug samples, to providers to induce the purchase of Schering products for which payment was made through federal health care programs; (ii) selling misbranded or unapproved drugs; (iii) submitting false wholesale pricing information for its pharmaceutical products to the government; and (iv) destroying evidence and obstructing justice relating to the government's investigation. *See* Schering-Plough Press Release dated May 30, 2003, "Schering Plough Provides Update on Previously Reported Investigation by U.S. Attorney for District of Massachusetts." Schering's Form 10-K for the year 2000 stated that this investigation focused on "whether the AWP set by pharmaceutical companies for certain drugs improperly exceeds the average prices paid by dispensers. . . and other pricing and/or marketing practices."

490. Schering took charge of \$150 million for the fourth quarter of 2002 to reflect its estimate of the likely legal liability from the above government probe. The primary basis for the government investigation was the federal anti-kickback statute, which prohibits pharmaceutical companies from giving money or other items of value to doctors in exchange for prescribing particular products to Medicaid patients.

491. Both Schering and Warrick are among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

492. Schering also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

493. The Schering Group is also under investigation by the Attorneys General of California, Massachusetts, Minnesota, Montana, Ohio, Pennsylvania and Wisconsin.

494. Schering was among the drug companies Congressman Stark investigated for improper Medicare/Medicaid pricing practices.

RR. SERONO

495. As set forth in detail in Exhibit A, the Westchester Medicaid Program spent over \$55,000 for Serono drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

496. Westchester alleges an intentionally false and misleading AWP for each Serono drug listed on Exhibit A.

497. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Serono drugs for which Westchester seeks relief.

498. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$31,000 for Serono's Serostim. Westchester's most popular dosage of Serostim was the 6 mg vial. The estimated overcharge for this dosage as a result of Serono's false AWPs is at least 27%. This translates into an overpayment of over \$8,000 by the Westchester Medicaid Program. *See* Exhibit B.

499. In January 2004, Serono announced that it was under investigation by federal and state officials in respect of its marketing practices for its AIDS-related drug

Serostim, one of the drugs for which New York seeks damages. The investigation focuses on possible improper sales, improper billing of State Medicaid programs and improper financial incentives to encourage doctors and pharmacists to prescribe the drug.

500. Serono received a subpoena from the U.S. Attorney's office in Boston in 2001 requesting nearly 10 years worth of documents pertaining to Serostim and in 2002 the company received similar requests from authorities in California, Florida, Maryland and New York. The criminal and civil investigations focus on whether the company violated federal and state false claims acts or anti-kickback laws, which prohibit drug companies from offering incentives to doctors to prescribe a drug covered by the government, individuals familiar with the investigations say, according to the Journal.

SS. TAKEDA

501. As set forth in detail in Exhibit A, the Westchester Medicaid Program spent over \$392,000 for Takeda drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

502. Westchester alleges an intentionally false and misleading AWP for each Ivax drug listed on Exhibit A

503. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Takeda drugs for which Westchester seeks relief.

504. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$392,000 for Takeda's Actos. Westchester's most popular dosage of Actos was the 30 mg tablet. The estimated overcharge for this dosage as a result of Takeda's false AWPs is at least 15%. This translates into an overpayment of over \$60,000 by the Westchester Medicaid Program. *See* Exhibit B.

TT. TAP PHARMACEUTICAL

505. As set forth in detail in Exhibit A, the Westchester Medicaid Program spent over \$1.5 million for TAP drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

506. Westchester alleges an intentionally false and misleading AWP for each TAP drug listed on Exhibit A.

507. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain TAP drugs for which Westchester seeks relief.

508. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$1.2 million for TAP's Prevacid. Westchester's most popular dosage of Prevacid was the 30 mg capsule DR. The estimated overcharge for this dosage as a result of TAP's false AWPs is at least 25%. This translates into an overpayment of over \$318,000 by the Westchester Medicaid Program. *See* Exhibit B.

509. In connection with the wrongful conduct described herein, TAP has been investigated by the Department of Justice. In addition, on October 13, 2001, the United States Attorney in Boston, Massachusetts announced that TAP, a corporation that arose from a partnership between Takeda Chemical Industries Ltd. and Abbott Laboratories, a defendant herein, had agreed to pay \$875 million to resolve criminal charges and civil liabilities in connection with its fraudulent pricing and marketing practices for the drug named Lupron®. As part of the agreement:

510. TAP agreed to plead guilty to a conspiracy to violate the Prescription Drug Marketing Act, 21 U.S.C. §§ 331(t) and 333(b), and to pay a \$290 million criminal fine, the largest criminal fine ever in a health care fraud prosecution. The plea

agreement between the United States and TAP specifically stated that TAP's criminal conduct caused the Government losses of \$145,000,000;

511. TAP agreed to pay the United States Government \$559,483,560 for filing false and fraudulent claims with the Medicare and Medicaid programs as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct;

512. TAP agreed to pay the fifty states and the District of Columbia \$25,516,440 for filing false and fraudulent claims with the States, as a result of TAP's drug pricing and marketing misconduct, and for TAP's failure to provide state Medicaid programs TAP's Best Price for Lupron®, as required by law;

513. TAP agreed to comply with the terms of a sweeping Corporate Integrity Agreement that, among other things, significantly changes the manner in which TAP supervises its marketing and sales staff and ensures that TAP will report to the Medicare and Medicaid programs the true average sale price for drugs reimbursed by those programs;

514. Abbott and Takeda (the TAP co-venturers) agreed to cooperate fully with the ongoing government investigation of TAP and its former officers and employees in exchange for the United States declining prosecution of Abbott and Takeda for conduct relating to Lupron.

515. An indictment was unsealed in the District of Massachusetts against six current or former TAP employees (including an account executive, three District Managers, a National Accounts Manager and the former Vice President of Sales), and a urologist, alleging that they conspired to (i) bill Medicare for free samples of Lupron® and (ii) market Lupron® using the "spread" and the "return to practice" program.

516. At a hearing in the criminal matter, which has an extensive record, United States District Court Judge William G. Young found:

This has been a gross abuse of the Medicare/Medicaid repayment system, knowing, intelligent. You have demonstrated, and it's all been confirmed in open court, and I don't want anyone forgetting about the fact that this company, not under its present management, knowingly abused the public trust in a most, and I use my words carefully, despicable way.

United States v. TAP Pharm. Prods., Inc., No. CR-01-10354-WGY (D. Mass. Dec. 6, 2001).

517. The TAP Defendants also have been sued in connection with their fraudulent pricing and marketing practices for Lupron, one of the drugs at issue here. *Russano v. Abbott Laboratories*, No. 01-6982 (N.D. ILL. filed Sept. 7, 2001).

518. TAP also is the subject of the investigation referred to above led by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is abusing the nominal price exception to the Best Price reporting requirements.

519. In connection with the wrongful conduct described herein, TAP has been sued by the Attorneys General of the States of Pennsylvania and Wisconsin.

UU. TEVA

520. As set forth in detail in Exhibit A, the Westchester Medicaid Program spent over \$682,000 for Teva drugs in 2002. The specific drugs for which Westchester seeks relief are set forth in Exhibit A hereto.

521. Westchester alleges an intentionally false and misleading AWP for each Teva drug listed on Exhibit A

522. Certain multisource or generic Teva drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWP's. N.Y. Soc. Serv. L. § 367-a(9).

523. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Teva drugs for which Westchester seeks relief.

524. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$28,000 for Teva's Fluoxetine HCL. Westchester's most popular dosage was the 40 mg capsule, for which there was no FUL for the majority of 2002. *See* Exhibit C. The estimated overcharge for this dosage as a result of Teva's false AWP is at least 56%. This translates into an overpayment of over \$15,000 by the Westchester Medicaid Program. *See* Exhibit B.

525. Teva is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

VV. UCB PHARMA

526. As set forth in detail in Exhibit A, the Westchester Medicaid Program spent over \$132,000 for UCB Pharma drugs in 2002. The specific drugs for which Westchester seeks relief are set forth in Exhibit A hereto.

527. Westchester alleges an intentionally false and misleading AWP for each UCB Pharma drug listed on Exhibit A

528. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain UCB Pharma drugs for which Westchester seeks relief.

529. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$132,000 for UCB Pharma's Keppra. Westchester's most popular dosage was the 500 mg tablet. The estimated overcharge for this dosage as a result of UCB Pharma's false

AWPs is at least 32%. This translates into an overpayment of over \$42,000 by the Westchester Medicaid Program. *See* Exhibit B.

WW. THE WATSON GROUP

530. As set forth in detail in Exhibit A, the Westchester Medicaid Program spent over \$368,000 for Watson Group (Watson and Watson Pharma (formerly Schein)) drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

531. Westchester alleges an intentionally false and misleading AWP for each Watson Group drug listed on Exhibit A.

532. Certain multisource or generic Watson Group drugs listed in Exhibit A were reimbursed at certain times based on the FUL, *see* Exhibit C, which, as explained above, is based on intentionally false and inflated AWP's. N.Y. Soc. Serv. L. § 367-a(9).

533. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Watson Group drugs for which Westchester seeks relief.

534. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$46,000 for Watson's Metformin HCL. Westchester's most popular dosage was the 500 mg tablet, for which there was no FUL in 2002. *See* Exhibit C. The estimated overcharge for this dosage as a result of Watson's false AWP's is at least 41%. This translates into an overpayment of over \$18,000 by the Westchester Medicaid Program. *See* Exhibit B.

535. In connection with the wrongful conduct described herein, Watson has been investigated by at least the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorneys General for

the states of California, Massachusetts, Montana, Pennsylvania and Wisconsin. Schein, Watson's subsidiary since 2000, has been investigated by the Office of the Attorney General of Texas in connection with a state investigation of "possible false reporting of information regarding the marketing of and prices for drugs" used to establish reimbursement rates for Texas Medicaid drugs, and has received notices or subpoenas from the attorneys general of various other states, including Florida, Nevada, California, Texas and New York. The publicly available results of these investigations confirm Watson's routine practice of reporting false and inflated wholesale price information and non-compliance with rebate obligations.

536. Schein also reported in its 10-Q for the quarterly period ended June 24, 2000, that it was a defendant in a federal *qui tam* action brought in 1995 under the U.S. False Claims Act in the Federal District Court for the Southern District of Florida. Schein stated that it "believe[d] that the matter relates to pharmaceutical pricing issues and whether 19 allegedly improper efforts by pharmaceutical manufacturers led to increased payments by Medicare and/or Medicaid."

537. Watson also is among the pharmaceutical companies referred to above now under investigation by the House Committee of Energy and Commerce for possible improper pricing practices and failures to comply with Best Price rebate requirements.

XX. WYETH

538. As set forth in detail in Exhibit A, the Westchester Medicaid Program spent over \$1.1 million for Wyeth drugs in 2002. The specific drugs for which Westchester seeks relief include those set forth in Exhibit A hereto.

539. Westchester alleges an intentionally false and misleading AWP for each Wyeth drug listed on Exhibit A.

540. Exhibit B sets forth Westchester's preliminary estimate of the extent of the overcharge on certain Wyeth drugs for which Westchester seeks relief.

541. As an example, in 2002 alone, the Westchester Medicaid Program spent over \$273,000 for Wyeth's Protonix. Westchester's most popular dosage of Protonix was the 40 mg tablet EC. The estimated overcharge for this dosage as a result of Wyeth's false AWP is at least 18%. This translates into an overpayment of over \$48,000 by the Westchester Medicaid Program. See Exhibit B.

542. Wyeth also is the subject of the investigation referred to above by Senators Grassley and Baucus of the Senate Finance Committee regarding whether it is inappropriately using the nominal price exception to the Best Price reporting requirements.

543. Wyeth also is the subject of an investigation by the Office of the Inspector General of the Office of Personnel Management concerning marketing practices for mental health drugs.

VII. DAMAGES TO THE WESTCHESTER COUNTY MEDICAID PROGRAM

544. The Westchester County Medicaid Program paid over \$103.5 million for prescription drugs for Westchester residents in 2003. A substantial portion of this huge sum is the result of the inflation of prescription drug prices pursuant to the AWP scheme alleged herein, and the failure to pay the full rebate amounts required by law.

545. Applying even the most conservative estimates of improper AWP spread and failures to report accurate Best Prices or pay proper rebates, these abuses result in millions of dollars in excessive payments by Westchester for Medicaid-covered drugs.

546. Westchester now seeks, *inter alia*, to recover the overpayment. Defendants' misconduct has unjustly enriched the defendants at the expense of New York's health care system, and ultimately, taxpayers in Westchester and State and nationwide.

VIII. FRAUDULENT CONCEALMENT

547. By controlling the process by which the AWP's or other wholesale price information for covered drugs were inflated and reported falsely to publishers, each defendant concealed its fraudulent conduct from Westchester. Each defendant prevented Westchester from knowing what the actual pricing structures for the covered drugs were, and concealed the standard discounts, chargebacks, off-invoice transactions, free samples and other financial incentives routinely provided to lower the actual costs for its drugs.

548. Each defendant concealed its fraudulent conduct by instructing drug distribution chain intermediaries not to report the prices they paid for the covered drugs.

549. Each defendant worked with and motivated provider and drug distribution chain intermediaries to halt investigations or changes in the AWP system.

550. Each defendant concealed that its calculation of Medicaid rebates, based on Best Price and AMP, did not account for all discounts, rebates or incentives as required by law.

551. Each defendant further concealed the true Best Prices from the federal agencies to which it reports those data.

552. Each defendant concealed that it was not paying proper rebates to the states.

553. Each defendant purposely concealed its pricing structures, promotional practices and sales figures for the covered drugs.

554. Each defendant's efforts to conceal its pricing structures for the drugs at issue is evidence that it knew that its conduct was fraudulent.

555. Thus, each defendant concealed that (i) its AWP's were highly inflated for the express purpose of causing Westchester to overpay for the covered drugs, (ii) it was

manipulating the AWP of the covered drugs, (iii) the AWP bore no relationship to the prices paid for, or the pricing structure of, the covered drugs and (iv) it was not accurately reporting its Best Prices and not accurately calculating its Medicaid rebates.

556. Unaware of the true facts about the pricing of the covered drugs, and statutorily obligated to a 25% Medicaid contribution, Westchester has paid and continues to pay for them based upon and in reliance on the AWP.

557. Westchester has been diligent in pursuing an investigation of the claims asserted in this Complaint. Only in the wake of recent Congressional hearings, DOJ, OIG and HHS reports, and settlements has Westchester become informed of or placed on notice regarding the extent of defendants' fraudulent conduct.

558. Westchester has been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on its part. Westchester could not reasonably have discovered the fraudulent nature of the published AWP and of the Medicaid rebate amounts calculated by defendants. Because of their knowing, affirmative, and active concealment of the fraudulent nature of pricing information, defendants are estopped from relying on any statutes of limitations.

559. Any applicable statutes of limitations have been tolled by defendants' knowing and active concealment and denial of the facts alleged herein. At all times relevant the defendants have been and are under a continuing duty to disclose to Westchester that the AWP they reported or caused to be reported bear no relationship to the actual prices paid for their drugs, and that the Medicaid rebates that they pay are reduced by the use of false and inaccurate pricing information.

CLAIMS FOR RELIEF

COUNT I
VIOLATION OF FEDERAL MEDICAID STATUTE, 42 U.S.C. § 1396r-8 (FAILURE TO COMPLY WITH FEDERAL MEDICAID REBATE PROVISION)

560. Westchester realleges and incorporates the preceding paragraphs as if fully set forth herein.

561. Each of the defendant pharmaceutical companies is a manufacturer of a drug covered by Medicaid.

562. Pursuant to 42 U.S.C. § 1396r-8, each of the defendant pharmaceutical manufacturers of single source and brand name innovator drugs entered into a rebate agreement with the Medicaid program pursuant to which the defendant agreed to report its Best Price.

563. In keeping with their artificial price inflation scheme, each defendant did not report the actual Best Price but instead reported incorrect Best Prices by, *inter alia*, excluding routine discounts (*e.g.*, volume and prompt pay discounts and discounts to repackagers), rebates, off-invoice transactions, free samples and other inducements offered to participants in the drug distribution chain that resulted in lower prices than the prices reported to the Medicaid Program.

564. Each of the defendants violated 42 U.S.C. § 1396r-8 by their systematic submission of untrue, incomplete, inaccurate, and misleading information used to determine the amount of rebates under the Medicaid program.

565. As set forth herein, acting with the intent to defraud and in order to obtain authorization to qualify as a provider and to provide specific goods, each defendant made or caused to be made false statements and incorrect payments while promising that it would comply with the mandates of 42 U.S.C. § 1396r-8.

566. Defendants knew, or by virtue of their position, authority or responsibility should have known, of the falsity of pricing information submitted and that the rebates they were paying were incorrectly calculated.

567. As a result of defendants' inaccurate reporting of Best Price, defendants did not comply with their obligations pursuant to the Federal Medicaid rebate provision and Westchester was deprived of a portion of the rebates to which it was entitled.

568. Westchester is within the class of entities for whose benefit the rebate provision was enacted.

569. Medicaid pharmacy costs for Westchester residents are higher than they would have been if defendants had accurately reported Best Price. Westchester has therefore suffered actual injury as a direct result of defendants' misconduct. That injury would be redressed through a favorable decision on this claim.

COUNT II
VIOLATION OF N.Y. SOCIAL SERVICES LAW § 367(A)(7)(d) (FAILURE TO
COMPLY WITH STATE MEDICAID REBATE PROVISION)

570. Westchester realleges and incorporates the preceding paragraphs as if fully set forth herein.

571. Each of the defendant pharmaceutical companies is a manufacturer of a drug covered by Medicaid.

572. The rebate provision, 42 U.S.C. § 1396r-8, is incorporated by New York State's Medicaid statute. *See* New York Social Services Law § 367-(a)(7)(d). New York law expressly provides that each of the defendants who have executed a rebate agreement are to be paid pursuant to that agreement.

573. As set forth herein, acting with the intent to defraud and in order to obtain authorization to qualify as a provider and to provide specific goods, each defendant made or caused to be made false statements and incorrect payments while promising that it would comply with the mandates of 42 U.S.C. § 1396r-8.

574. Each defendant thereby violated N.Y.Soc. Serv. L. § 367-(a)(7)(d) in that it submitted untrue, incomplete, inaccurate, and misleading information used to determine the amount of reimbursement under the Medicaid program and in that it paid incorrectly calculated rebates to the states.

575. Defendants knew, or by virtue of their position, authority and responsibility should have known, of the falsity of the pricing information submitted and that the rebates they were paying were incorrectly calculated.

576. As a result of defendants' inaccurate reporting of Best Price, defendants did not comply with their obligations pursuant to the State Medicaid rebate provision and Westchester was deprived of a portion of the rebates to which it was entitled.

COUNT III

VIOLATION OF NEW YORK SOCIAL SERVICES LAW § 145-b (OBTAINING PUBLIC FUNDS BY FALSE STATEMENTS)

577. Westchester realleges and incorporates the preceding paragraphs as if fully set forth herein.

578. New York Social Services Law § 145-b provides that “[i]t shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for ... supplies furnished ... pursuant to” the Medicaid Program.

579. By engaging in the acts and practices described above, defendants have knowingly made false statements and representations or engaged in a fraudulent scheme on behalf of themselves and others, resulting in the overpayment of public funds for defendants' prescription drugs covered by the New York Medicaid Program in violation of Soc. Serv. L. § 145-b.

580. Defendants' conduct violated and continues to violate Social Services Law § 145-b because defendants, and each of them, by means of their false statements and representations and deliberate concealment of material facts attempted to obtain and did in fact obtain payment from public funds for supplies furnished pursuant to this chapter. Defendants made false "statements or representations" under § 145-b(1)(b) because they gave "a [false] report of data which serves as the basis for a claim or a rate of payment."

581. Defendants have "attempted to obtain and did obtain payment from public funds for supplies" under § 145-b(1)(c) because they obtained a portion of public funds from which payment was made, and because "public funds [we]re used to reimburse ... an entity from which payment was obtained." N.Y. Soc. Serv. L. § 145-b.

582. Defendants also have made false statements or representations "on behalf of others...to obtain payment from public funds in violation of N.Y. Soc. Serv. L. § 145-b.

COUNT IV

VIOLATION OF NEW YORK DEPARTMENT OF HEALTH REGULATIONS 18 N.Y.C.R.R. § 515.2(b)(4) and (5)

583. Westchester realleges and incorporates the preceding paragraphs as if fully set forth herein.

584. The Regulations of the New York City Department of Health, 18 N.Y.C.R.R. § 515.2(b)(4), provide that “[c]onversion of a medical assurance payment, or any part of such payment, to a use or benefit other than for the use and benefit intended by the medical assistance program,” is an “unacceptable practice” within the New York Medicaid Program.

585. The Regulations of the New York Department of Health, 18 N.Y.C.R.R. § 515.2(b)(5) provide that an “Unacceptable Practice” within the Medicaid program is committed by “offering or paying either directly or indirectly any payment (including any kickback, bribe, ... rebate or discount), whether in cash or in kind, in return for purchasing, ... ordering or recommending any medical care, services or supplies for which payment is claimed under the program,” “[u]nless the discount or reduction in price is disclosed to the client and the department and reflected in a claim,”

586. By engaging in the acts and practices described above, defendants have engaged in and continue to engage in Unacceptable Practices within the New York Medicaid Program as defined at 18 N.Y.C.R.R. § 515.2(b)(4) and (5).

COUNT V

BREACH OF CONTRACT

587. Westchester realleges and incorporates by reference the preceding paragraphs as if fully set forth herein.

588. As required by 42 U.S.C. § 1396r-8, and to effectuate its purpose of reducing state Medicaid drug expenditures, each defendant entered into a Rebate Agreement with the Secretary of HHS.

589. The Secretary of HHS entered into this Rebate Agreement, “on behalf of the States.”

590. The Medicaid statute provides that “the State *or local agency* administering such plan will take all reasonable measures to ascertain the legal liability of third parties for any overcharges and submit to the Secretary of Health and Human Services a plan for pursuing such claims. 42 U.S.C. § 1396a (a)(25)(A) (emphasis added).

591. In any case where such a legal liability is found to exist . . . and where the amount of reimbursement the State can reasonably expect to recover exceeds the costs of such recovery, the State or local agency will seek reimbursement for such reimbursement to the extent of such legal liability. 42 U.S.C. 1396a (a)(25)(B).

592. New York’s plan requires local social service districts to pay 25 percent of their Medicaid pharmacy costs, N.Y. Soc. Serv. L. §§ 360a, 363. It expressly authorizes local social service districts to file suit and seek treble damages for any knowing overcharge the Medicaid program, N.Y. Soc. Serv. L. § 145-b, and provides that amounts collected under that provision shall be apportioned between the local social service district and the state. N.Y. Soc. Serv. L. § 145-(b)(2) (“Amounts collected . . . shall be apportioned between the local services district and the state.”).

593. At the time each defendant entered into a Rebate Agreement, the Secretary of HHS expressly had approved New York State’s Medicaid plan, including these provisions that authorize local social service districts, like Westchester, to sue for Medicaid fraud and that expressly impose a 25% contribution on Westchester.

594. New York Social Services Law § 367-a(7)(D) expressly states that if any defendant has entered into such rebate agreement with HHS, reimbursement for covered outpatient drugs shall be made only subject to 42 U.S.C. § 1396r-8.

595. Westchester, like New York State, was an intended third-party beneficiary of these rebate agreements.

596. The Secretary of HHS acted as the agent of Westchester and the State in executing the rebate agreements. The rebate agreements expressly provide that the Secretary is entering into the agreements “on behalf of the states.” Westchester is a local social services district for the purposes of administration of the State Social Services Law, N.Y. Soc. Serv. L. §§ 55, 61-62, and is therefore subsumed under the State in New York’s statutory scheme.

597. As set forth herein, contrary to the express requirements of the Rebate Agreements, each defendant did not report accurate Best Prices for its drugs or pay correct Medicaid rebates.

598. Rather, each defendant reported false and inflated Best Prices that, among other things, excluded routine discounts including prompt pay and bundled discounts, rebates, chargebacks and other inducements and incentives offered to drug selecting entities to create market share, and abused the nominal price exception.

599. Defendants have therefore breached their rebate agreements and caused massive foreseeable damage to Westchester, an intended third-party beneficiary of the rebate agreement.

COUNT VI

UNFAIR TRADE PRACTICES (Violations of N.Y. Gen. Bus. Law § 349 *et seq.*)

600. Westchester realleges and incorporates by reference the preceding paragraphs as if fully set forth herein.

601. As set forth with particularity herein and in Exhibit A, defendants herein have intentionally and wrongfully reported inaccurate, false and misleading wholesale pricing information for the covered drugs.

602. As alleged herein, this AWP scheme was designed to increase demand for defendants' products and is consumer oriented.

603. Defendants' intentional wrongful acts caused direct damage to tax paying consumers and Westchester by wrongfully increasing Medicaid expenditures on behalf of Westchester's Medicaid Program.

604. The defendants' intentional misconduct directly has damaged the public and Westchester. Westchester is statutorily required to pay 25% of the Medicaid pharmacy costs attributable to its Medicaid recipients. N.Y. Soc. Serv. L §§ 367-b, 363-b(2).

605. New York's Medicaid statute expressly states, *inter alia*, that "[m]edical assistance for needy persons is hereby declared to be a matter of public concern and a necessity in promoting the public health and welfare." Social Services Law § 363. Defendants' deceptive acts, as described herein, are in direct contravention of this statutorily articulated public policy. Defendants' practices were consumer-oriented and continue to have a broad impact on consumers and the taxpaying public.

606. Westchester is required by State law to balance its budget. Every dollar spent on Medicaid is a dollar that cannot be spent elsewhere.

607. Defendants' conduct as alleged in this Complaint constitutes deceptive acts or practices in that:

(a) Defendants have failed to disclose material facts in the conduct of trade or commerce in that they have not disclosed that the wholesale pricing information they

submit does not reflect the true wholesale prices of the drug products they sell, and that the Best Prices they report are not the actual Best Prices offered to other commercial entities, but are instead inflated in order to drive up the prices paid for medications by Westchester and deny Westchester proper Medicaid rebates;

(b) Defendants have made false or misleading statements of facts concerning the price of goods in that they have lied about the true wholesale pricing information and true Best Prices paid for their medications, which they know are the bases of Westchester's Medicaid pharmacy cost payments, in order to drive up the prices paid by Westchester through Medicaid and deny Westchester proper Medicaid rebates;

(c) Defendants have knowingly made false representations in a transaction by representing that the wholesale pricing information provided is an accurate reflection of the wholesale prices paid for their drugs, and that their reported Best Prices are in fact the Best Prices offered to a commercial entity for their drugs; and

(d) Defendants have violated state and federal statutes and regulations relating to the sale or lease of goods including, without limitation, the Best Price requirement of the Medicaid statute, New York's Social Services Law, § 367-a, and § 145-b. These statutory and regulatory violations serve, at minimum, as predicates for the violation of New York's Gen. Bus. Law § 349.

608. The wrongful conduct alleged in this Complaint occurs and continues to occur in the ordinary course of defendants' business and has caused great harm to Westchester and the consumers who live there. Westchester has suffered actual damages because it has had to overpay millions of dollars in Medicaid pharmacy costs as a direct and proximate result of defendants' misleading and deceptive practices.

COUNT VII

FRAUD

609. Westchester realleges and incorporates the preceding paragraphs as if fully set forth herein.

610. As detailed in the Complaint and Exhibit A, defendants have engaged in actual fraudulent reporting of pricing information on which Medicaid reimbursements are based, and have acted intentionally and with actual malice.

611. Defendants have made false representations with knowledge of their falsity, have concealed material facts with the purpose of overcharging Westchester and Westchester has relied upon such misrepresentations. Direct, proximate and foreseeable injury has occurred as a result of such foreseeable and statutorily required reliance.

612. Defendants also had knowledge of facts or intentionally disregarded facts that created a high probability of injury to Westchester, and deliberately proceeded to act in conscious or intentional disregard of, or with indifference to, the high probability of this injury.

613. New York's Social Service Law § 366-b expressly provides that "any person who, with intent to defraud, presents for allowance or payment any false or fraudulent claim for furnishing services or merchandise, or who knowingly submits false information for the purpose of obtaining greater compensation than that to which he is legally entitled for furnishing services or merchandise, or knowingly submits false information for the purpose of obtaining authorization of furnishing services or merchandise under this title, shall be guilty of a class A misdemeanor...".

614. Defendants' knowing and intentional submission of inflated AWP's or other wholesale pricing data to publishers for the express purpose of effectuating the AWP

scheme alleged herein, and their knowing and intentional failures to report accurate Best Prices and failure to pay correct Medicaid rebates constitute intentional frauds pursuant to common law and New York Social Services Law § 366-b.

COUNT VIII

UNJUST ENRICHMENT

615. Westchester realleges and incorporates by reference the preceding paragraphs as if fully set forth herein.

616. To the extent the court determines there is no contractual relationship between Westchester and the defendants, as a direct and proximate result of the unlawful conduct described above, defendants have been and will continue to be unjustly enriched.

617. Defendants have benefited from their unlawful acts through the increased sale of covered drugs with the greatest spread. It would be inequitable for defendants to retain any of their ill-gotten gains earned as a result of the scheme alleged herein, which gains would not exist but for the overpayments made by the Westchester Medicaid Program and other Medicaid payors.

618. Westchester is entitled to an accounting and the establishment of a constructive trust consisting of all overcharges paid by the Westchester Medicaid Program for covered drugs.

PRAYER FOR RELIEF

WHEREFORE, plaintiff Westchester prays for judgment against each and every defendant, jointly and severally, as follows:

619. Adjudging and decreeing that defendants engaged in the intentional fraudulent conduct alleged herein in violation of N.Y. Soc. Serv. L. §§ 367-a(7)(d), 366-b, 145-b and 42 U.S.C. § 1396r-8 and 18 N.Y.C.R.R. 515.2(b)(4) and (5).

620. Awarding Westchester actual, statutory, treble and all other available money damages, with interest, for defendants' violation of N.Y. Gen. Bus. Law § 349 in an amount to be determined at trial;

621. Awarding Westchester actual, statutory, treble, punitive and all other available money damages, with interest, for defendants' violation of N.Y. Soc. Serv. L. § 145-b in an amount to be determined at trial;

622. Awarding Westchester actual and compensatory damages in an amount to be determined at trial, with interest, for defendants' breach of contract;

623. Awarding Westchester actual and punitive damages in an amount to be determined at trial, with interest, for defendants' intentional fraud in respect of matters of significant public interest;

624. Ordering defendants each to prepare an accounting to determine the amounts defendants have illegally profited at the Westchester Medicaid Program's expense, and disgorgement of such monies, with interest;

625. Imposing a constructive trust and ordering defendants to pay restitution to the Westchester Medicaid Program in the amount the Westchester Medicaid Program has been overcharged for covered drugs, with interest;

626. Awarding plaintiff the costs of the suit, including costs, reasonable attorneys' and experts' fees pursuant to N.Y. Gen. Bus. Law § 349, N.Y. Soc. Serv. L. § 145-b, and any other applicable federal and state claims.

627. Such other further and different relief as the Court deems just and proper.

Dated: January 26, 2005.

Respectfully submitted,

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By: 

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Aaron D. Hovan (AH 3290)

CERTIFICATE OF SERVICE

I hereby certify that I, Aaron D. Hovan, an attorney, caused a true and correct copy of the foregoing County of Westchester v. Abbott Laboratories, Inc., *et. al* Amended Complaint, dated January 26, 2005 to be served on all counsel of record electronically on January 26, 2005, pursuant to Section D of Case Management Order No. 2.

/s/ Aaron D. Hovan

Aaron D. Hovan

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